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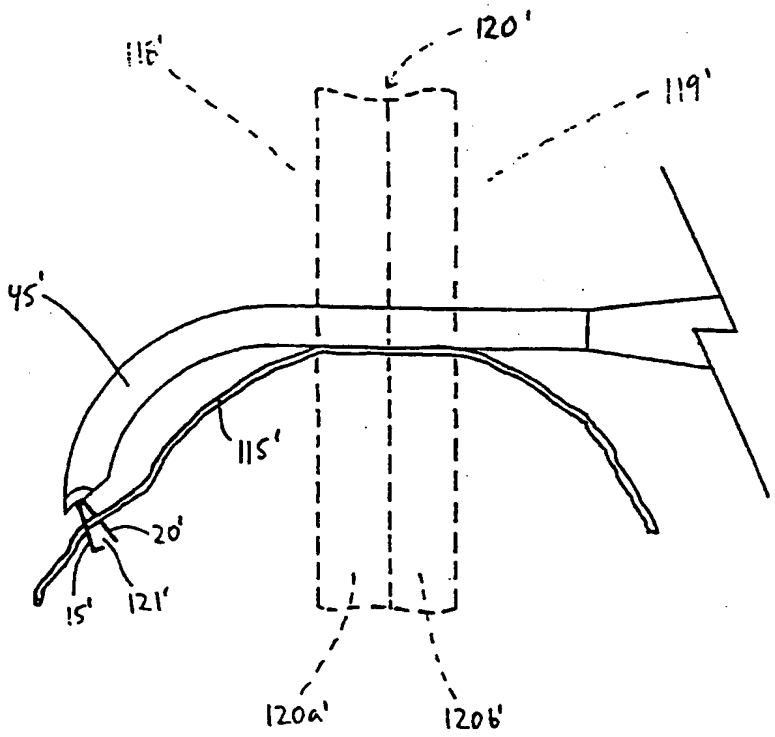
(57) Abstract

The present invention is directed to novel surgical systems that include a combination of an improved bone fastener, suture grasping device and/or suture throw rundown instrument. The systems can be used, e.g., for endoscopic procedures to repair and reattach soft tissues. The systems include a bone fastener comprising an expandable member having an axial channel and an elongated element inserted into the axial channel. The expandable member is configured to be insertible into a bore drilled in bone. The member is expanded using a continuous, compressive force (i.e., pressure without impulse or impact). The expandable member is grasped at its distal end throughout the emplacement procedure and is axially released from an emplacement tool. The systems can further include a suture grasping device comprising a rigid, hollow shaft, a rod, a first elongate wire-like element, a second elongated wire-like element, and an actuation device. The systems further include a suture throw rundown element comprising a handle assembly having first and second handle members movably connected for movement relative to one another, an elongate rod releasably secured to the first handle member.



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SURGICAL SYSTEM AND METHOD FOR THE REATTACHMENT OF SOFT TISSUE TO BONE

Reference to Related Applications

This application is a continuation-in-part of co-pending U.S. application serial number US 08/163,130, filed December 6, 1993, which is a continuation-in-part of U.S. application serial number 07/765,445, filed September 25, 1991 (now U.S. Patent 5,268,001), which is a continuation-in-part of U.S. patent application serial number 07/588,055, filed September 25, 1990 (now abandoned).

This application is also a continuation-in-part of U.S. application serial number 08/200,883, filed February 23, 1994, entitled "Surgical Grasping and Suturing Device," which is a continuation-in-part of United States patent application Serial No. 08/097,154, filed on July 26, 1993, entitled "Suture Grasping Device".

This application is also a continuation-in-part of U.S. application serial number 08/234,642, filed April 28, 1994, entitled "Surgical Instrument," which is a continuation-in-part of my prior co-pending U.S. patent application Serial No. 07/959,121, filed October 9, 1992, also entitled "Surgical Instrument"

The contents of the aforementioned applications (and patent) are incorporated herein by reference.

Background of the Invention

A variety of techniques are available for affixing objects such as soft tissue to bone. The oldest technique utilizes thread passed through the bone and the tissue to sew the tissue down to the bone. Many sizes, shapes and types of suture and suture needles are available to accomplish this task. Today, this method is still used for repair of tendons and ligaments in older osteoarthritic patients, although passing a suture through bone is generally difficult and tedious.

Soft tissue repairs also have been accomplished with metal screws or staples that attach soft tissue to bone. Metal screws and/or staples are,

however, subject to corrosion and consequent loss of structure. Moreover, the presence of metal in an anatomical site can interfere with imaging and diagnostic or therapeutic treatments near the site. For example, any metal implants may have to be removed by surgery prior to magnetic resonance imaging. Patient sensitivity to nickel ions and stainless steel implants has fueled a growing controversy regarding the use of materials containing high quantities of nickel including nickel-titanium alloys such as Nitinol. Also, it is almost impossible to adjust the compression exerted by screws and staples on soft tissue. Thus, these devices are not fully satisfactory for soft tissue repair.

Other devices employ a suture anchor installation affixed to an arc of wire or a plurality of barbs disposed on an outer surface of the suture anchor body. The barbs or arc of wire are set by applying traction to the suture. Unfortunately, it is not always possible to position the anchor at a precise location within a bone if an anchor is being drawn upwards in a bone hole by applying tension to a suture. Furthermore, many of the fastening devices require some type of impact or impulse to set the fastener in position. Impact emplacement or setting of bone/suture anchors may result in injury to the patient as well as placing unnecessary strain on the bone/suture fastener itself.

Human and animal surgery frequently requires the grasping, manipulating or cutting of tissue or other organic living matter at some distance from the surgeon's hands. In such cases endoscopic surgical methods are commonly employed that make it possible for skillful and precise surgery to be conducted despite the fact that the surgical site is a substantial number of inches from the point of initial incision in the person or animal being operated on. Endoscopic surgical procedures encompass both arthroscopic and laparoscopic surgery techniques. In endoscopic surgery, small incisions are made in the exterior surface of the person or animal being operated on, and the work being performed is observed by the operating surgeon by means of a an optical device known as an endoscope which is inserted into the person or animal through a

small incision. Endoscopic surgical techniques are displacing conventional open surgical techniques for many procedures, and hence there is a need for improved instruments for conducting such procedures.

A wide variety of surgical instruments have been devised for use in arthroscopic and laparoscopic surgical procedures, including instruments such as graspers, forceps and scissors for use in grasping, cutting or otherwise remotely manipulating bodily tissue and other matter during surgery.

A typical instrument employed in endoscopic surgery has a pair of articulated jaws, and a handle mechanism comprising two members, one movable with respect to the other, which can conveniently be manipulated so as to cause the jaws to open and close. Serrations, blades, cutting edges, or other features (depending upon the use for which the tool is intended) enable the jaws to perform various surgical functions, such as grasping or cutting. The articulated jaws are located at the distal end of a relatively long extension of the handle mechanism. The length of the extension is determined by the depth of the surgical site, while its cross-sectional dimensions are established by the maximum permissible incision size.

Many ingenious linkages have been devised for converting the surgeon's manual efforts at the handle end of the instrument into opening and closing of the tool's jaws. Most commonly, the surgical tool comprises a stationary handle member rigidly joined to a hollow outer shaft and a movable handle member pivotally attached to a coaxial inner shaft in the form of a tube or solid rod that is capable of reciprocal axial movement relative to the outer shaft, with the jaws being operatively coupled between the outer hollow shaft and the inner shaft member so as to open and close in accordance with relative axial movement of the outer and inner shafts. When the surgeon squeezes the stationary and movable handle members together, the outer and inner shafts coact in such a way as to make the jaws close. When the surgeon spreads the stationary and movable handle members apart, the motions are reversed and the jaws open. Publications illustrating the prior art include U.S. Patent No.

3,404,677 and the prior art cited therein, as well as the following references: U.S. Patents Nos. 4,836,205; 4,258,716; 4,084,594; 4,393,872; 5,026,375; 4,712,545; and 5,026,370.

Devices for grasping free suture ends during surgical procedures are well known in the art. In one such device, an elongated element is provided. This element has a flexible, closed loop at one of its ends. The elongate element is telescopically mounted inside a hollow shaft so that the loop can be alternately withdrawn into, or projected out of, the distal end of the shaft.

In use, this device is first set so that its loop is retracted into the shaft. Then the device is manipulated so that the distal end of the shaft is brought into the vicinity of a free end of the suture which is to be grasped. The loop then is projected out of the distal end of the shaft. The device is thereafter further manipulated so that the free end of the suture which is to be grasped extends through the loop. Finally, the loop surrounding the suture is retracted back into the shaft, thereby grasping the suture and holding it tightly against the distal end of the shaft.

While devices of the type described above work for their intended purpose, they also have several drawbacks. For example, it is often difficult (or impossible) to conveniently access a free end of a length of suture, even in those cases where some intermediate portion of the suture has been located. This is particularly true in closed surgeries where visibility is frequently quite limited and the available space at the surgical site is often restricted.

Furthermore, in many surgical procedures suture needs to be laced one or more times through one or more layers of tissue. Conventionally, such suturing is accomplished by attaching a needle to at least one free end of the suture. This needle is then manipulated using a needle holder so as to pass the suture through the tissue. Thereafter, a grasping device such as the one described above is used to snare a free suture end (or ends) for further manipulation or tying.

The need to use a needle and needle holder to pass the suture through

the tissue, and the need to use a separate grasping device to complete the suturing operation, can be inconvenient and cumbersome. This is particularly true in closed surgical procedures where the surgeon must operate through a small passageway leading from the skin of the patient to an internal surgical site. In such situations, the surgeon's visual and physical access to the surgical site is generally quite limited.

In view of the foregoing, an object of the invention is to provide improved surgical systems and, more particularly, improved systems for the repair and reattachment of soft tissues.

Still another object of the invention is to provide a bone fastener of simple design and construction, with improved an suture grasping device and/or an improved surgical instrument for suture throw rundown.

Yet other objects of the invention are to provide an improved system of bone fastener, suture grasping device and/or suture throw rundown instrument for endoscopic surgical procedures.

Still yet another object of the invention is to provide such a system for use in the repair and reattachment of soft tissues.

Summary of the Invention

The present invention is directed to novel surgical systems that include a combination of an improved bone fastener, suture grasping device and/or suture throw rundown instrument. The systems can be used, e.g., for endoscopic procedures to repair and reattach soft tissues.

According to one aspect of the invention, the systems include a bone fastener comprising an expandable member having an axial channel and an elongated element inserted into the axial channel. The expandable member is configured to be insertible into a bore drilled in bone. The member is expanded using a continuous, compressive force (i.e., pressure without impulse or impact). The expandable member is grasped at its distal end throughout the emplacement procedure and is axially released from an emplacement tool.

The fastener can include a cylindrical expandable member for insertion into an opening in a bone, the member including an outer surface for expandable engagement with an inner surface of the bone opening. An axial channel is defined in the expandable member, the channel extending at least partially between proximal and distal ends of said expandable member. An elongated, insertion element that is compressed into the expandable member is also part of the fastener. The insertion element has proximal and distal ends and a channel defined between the ends for engagement with a suture. Preferably, the insertion element includes a projection that expands the axial channel of the expandable member in an ineversible manner to obtain a press-fit with the bone opening.

The bone fastener can comprise a rivet for coupling an object to bone for use with an expandable member capable of insertion into an opening in a bone. The rivet includes an elongated insertion element adapted for compression into a distal end of the expandable member. The insertion element has a shaft with proximal and distal ends, an outer surface of said shaft including a radially outward projecting portion adapted to expand the expandable member. The distal end of the elongated insertion element includes a radially projecting portion adapted for engagement with a washer that contacts the object to be coupled. The washer, having upper and lower surfaces and a bore defined between the surfaces, is disposed around the shaft of the inserting element. The element is adapted for movement independent of the washer since the radial projection of the insertion element has a different radius of curvature than the washer.

The inventive systems can also include an apparatus, e.g., for use within an endoscope, for inserting fasteners as described above into bone. The apparatus can include an elongated, substantially hollow holder for the expandable member, an insertion element for engagement with an inner surface of the axial channel; a structure for axially releasing the expandable member from the holder when the expandable element is fully expanded within the bone

opening; a structure adapted for co-axial movement relative to the holder for placing the element into the axial channel of the expandable member; and a structure co-axially moveable within the hollow body for releasing the expandable member from the holder. In these regards, the expandable member can includes a structure for axially releasing the expandable member from the holding means. The structure may be a frangible membrane disposed intermediate the proximal end of the holding means and the distal end of the expandable member.

The inventive systems can further include a suture grasping device comprising a rigid, hollow shaft, a rod, a first elongate wire-like element, a second elongated wire-like element, and an actuation device.

The rigid, hollow shaft can include a proximal end, a proximal portion adjacent to the proximal end, a pointed distal end, a distal portion adjacent to the distal end, and a lumen extending between the proximal end and the distal end. In this regard, the inner and outer diameters of the proximal portion of the shaft can be larger than the inner and outer diameters of the distal portion of the shaft. Further, the distal portion of the shaft can be curved.

The rod can be a solid element having a proximal end and a distal end. The rod can be telescopically located in the proximal portion of the shaft. More specifically, the rod can have a longitudinal length slightly greater than the longitudinal length of the proximal portion of the shaft. Accordingly, the rod may be moved between (i) a proximal-most position wherein the distal end of the rod is spaced proximally from the point where the proximal and distal portions of the shaft meet; and (ii) a distal-most position wherein the distal end of the rod is substantially aligned with the point where the proximal and distal portions of the shaft meet.

The first and second wire-like elements each can have a proximal end and a distal end. The proximal ends of these two wire-like elements are attached to the distal end of the rod, whereby the two wire-like elements will move in conjunction with the rod. In addition, at least the distal portions of the

two respective wire-like elements can bend or flare away from each other. Furthermore, the first wire-like element can be bent radially inwardly immediately adjacent to its distal end so as to form a substantially hook-shaped configuration.

The actuation device can be attached to the proximal end of the shaft and to the proximal end of the rod. The actuation device can include a housing attached to the proximal end of the shaft. The housing can define a cylindrical cavity which is aligned with, and opens axially into, the lumen of the shaft. A trigger can be pivotally attached to the housing and extend into the cylindrical cavity. A piston-like element can be attached to the proximal end of the rod, and located in reciprocally sliding relation within the housing's cylindrical cavity. A spring can bias the piston-like element proximally so that the rod will normally assume its aforementioned proximalmost position. The piston-like element may be moved distally against the force of the spring by the trigger, so that the rod will assume its distalmost position.

The foregoing suture grasping device may be used to grasp and manipulate a piece of suture at a surgical site. Among other things, it may also be used to grasp a piece of suture and to pass that suture through one or more layers of tissue. The passage of suture through tissue may be accomplished either by pulling the suture through, or by pushing the suture through, the tissue. Multiple passes of suture may be used to suture two pieces of tissue together.

More particularly, in those cases where it is desired to pull a suture through tissue, the pointed distal end of the shaft is first forced through the tissue. Then the shaft is manipulated so as to bring its distal end substantially adjacent to the portion of the suture which is to be carried back through the tissue. Next, the trigger is activated so as to move the rod toward its distalmost position. This causes the distal ends of the wires to project out the distal end of the shaft so that the two wire elements flare away from each other. The suture grasping device is then manipulated further as needed so as

to position the suture in the gap between the first and the second wire-like elements.

The trigger is then released so as to allow the rod to return to its proximalmost position under the influence of the spring. As this occurs, the distal ends of the two wire-like elements retreat back into the distal portion of the shaft, with the two wire-like elements moving back toward one another as they re-enter the distal portion of the shaft. As the two wire-like elements retract, the hook at the distal end of the first wire-like element grapples the suture which is located between the two wire-like elements and carries it toward the distal end of the shaft. As the hook enters the distal end of the shaft, a portion of the suture is also drawn into the distal end of the shaft. The suture is captured in this position by the spring-biased hook acting in co-operation with the distal end of the shaft. If desired, the hook, the shaft and the suture may be sized so that the suture is tightly bound to the shaft at this point. Alternatively, the hook, the shaft and the suture may be sized so that the suture will be free to slide transversely relative to the hook when it is inside the distal portion of the shaft.

The distal end of the shaft is then withdrawn from the pierced tissue, carrying the grappled suture with it. Thereafter, the length of suture is released from the suture grasping device by squeezing the trigger again. This causes the wire-like elements to project out the distal end of the shaft in flaring relation to one another. The suture then is released from the suture grasping device by manipulating the tool and/or the suture so that the suture no longer sits in the gap between the distal ends of the two wire-like elements.

In those cases where it is desired to push a suture through tissue, a corresponding procedure is used. Specifically, the distal end of the shaft is first positioned substantially adjacent to the suture which is to be passed through the tissue. The trigger then is squeezed so as to project the two wire-like elements out the distal end of the shaft, in flaring relation to one another. Thereafter, the device is manipulated so as to position the suture in the gap between the

two wire-like elements. The trigger is then released so as to allow the distal ends of the two wire-like elements to retract back into the distal portion of the shaft under the influence of the spring, with the two wire-like elements moving back toward one another as they re-enter the distal end of the shaft. As this occurs, the hook grapples the suture and holds it against the distal portion of the shaft. The engagement of the suture with the distal end of the shaft is such that the point at the distal end of the shaft is located distally of the grasped suture and the

two wire-like elements.

In this configuration, the distal end of the shaft is then forced through the tissue, carrying the grappled suture with it. Once the distal end of the shaft is on the far side of the tissue, the trigger is squeezed again so as to project the two wire-like elements out the distal end of the shaft, in flaring relation to one another. The suture is then released from the suture grasping device by manipulating the tool and/or the suture so that the suture no longer sits in the gap between the distal ends of the two wire-like elements. Then the trigger is released so as to retract the distal ends of the two wire-like elements into the distal end of the shaft. Finally, the shaft is withdrawn from the tissue, leaving the suture extending through the tissue.

A suturing procedure requiring multiple passes of the suture through one or more layers of tissue can also be conveniently accomplished with such a device. For example, the suture grasping device might be used to first pull a length of suture through the tissue, and thereafter to push that same suture through the tissue at a location adjacent to the first pass of the suture through the tissue. Alternatively, the suture grasping device may be used to first push a length of suture through the tissue, and thereafter to pull that same suture through the tissue at a location adjacent to the first pass of the suture through the tissue.

A system according to the invention further includes a surgical instrument or tool comprising a handle assembly having first and second handle

members movably connected for movement relative to one another, an elongate rod releasably secured to the first handle member so as to form a fixed extension thereof, a tool head coupled to the rod having first and second members movable toward and away from one another, a tube (hollow shaft) coaxially and slidably surrounding the rod, with the tube having a first end slidably received in the handle assembly and a second end in position to be moved into and out of overlapping relation with said first and second members of said tool head, and drive means connecting said hollow tube and one of said handle members for causing said tube to shift axially relative to said rod between (1) a first retracted position when said one handle member is moved to a first position relative to the other handle member and (2) a second extended position when said one handle member is moved to a second position relative to said other handle member, said first and second members of said tool head being in a first open position relative to one another when said one handle member is in its said second position and being forced by said tube to close relative to one another when said one handle member is moved to its said first position.

According to a further aspect of the invention: (1) the tool head can be detached from the rod and replaced by another like or different tool head; (2) the tool head can be rotated relative to the handle assembly; (3) the rod, tool head and hollow tube can form a subassembly that is readily detachable from the handle assembly; and (4) the tool head may be electrified for monopolar cauterization.

The tool head can be arranged to allow the surgical instrument to be used to tie off suture that is extending from a surgical site. In this regard, the tool head includes means for running suture throws down the suture so as to form a knot adjacent to the surgical site, and means for thereafter severing the suture ends extending out of the knot. One method for tying off suture with such a device includes the steps of:

(1) forming a surgical throw in the suture ends extending away from a

surgical site;

(2) with the surgical instrument's tube in a first position, threading one of the suture ends through a first opening in the surgical instrument;

(3) sliding the other suture end through a second opening in the surgical instrument, and moving the surgical instrument's tube to a second position;

(4) while holding the suture ends taut, running the surgical throw toward the surgical site with the surgical instrument;

(5) moving the surgical instrument's tube back to its first position, thereby pulling the surgical throw tight;

(6) disengaging the two suture ends from the surgical instrument;

(7) repeating steps 1-6 as many times as necessary so as to form the desired surgical knot;

(8) with the surgical instrument's tube in its first position, positioning the surgical instrument adjacent to the suture ends extending away from the surgical knot; and

(9) moving the tube from its first position to its second position so as to sever the suture ends extending out of the knot.

According to still further aspects of the invention, a system as described above, is encased in a sterile tray or other receptacle for use by an operator at a site.

Still further aspects of the invention provide surgical methods comprising using bone anchors, suture grasping devices and/or suture throw rundown instruments of the types described above.

These and other aspects of the invention are evident in the attached drawings and in the description that follows.

Brief Description of the Drawings

Figure 1 is a cross-section through the expandable member of the present invention;

Figure 2 is a cross-section through an expandable member of the present invention in which the distal end is configured to form a radial projection;

Figure 3 is a cross-section through a rivet-type expandable member placed in a bone opening;

Figure 4 is a cross-section of an insertion element the present invention;

Figure 5 is a cross-section of another embodiment of an insertion element of the invention;

Figure 6 is a perspective view of another embodiment of an insertion element and washer of the present invention;

Figure 7 illustrates in a less diagrammatic cross-sectional view, a suture fastener of the invention emplaced in a pre-drilled hole in bone. This Figure shows deformation of the outer portion of expandable member within irregularities in the bone hole wall;

Figure 8 is a cross-section of an embodiment of the bone fastener in which a proximal projection extends out of the proximal end of the expandable member;

Figure 9 is a cross-section of a further embodiment of Figure 8;

Figure 10 is a cross-section of an elongated, slidable suture insertion element of Figure 5 in place within expandable element in a bone opening;

Figure 11 is a cross-section illustrating an insertion element rivet and washer of Figure 6 in place within expandable element in a bone opening;

Figure 12 is a diagram showing emplacement of expandable member within bone hole using a preferred holding means;

Figure 13 is a cross-section of one embodiment of expandable member and holding means of the invention;

Figure 14 is a cross-section of another embodiment of an expandable member and holding means of the invention;

Figure 15 is a cross-section of a frangible membrane of the invention;

Figure 16 is a cross-section of another embodiment of a frangible

membrane of the invention;

Figure 17 is a cross-section showing emplacement of a bone fastener within a bone hole using an apparatus of the present invention;

Figure 18 illustrates one step in the expansion of the expandable member using the method and apparatus of the invention;

Figure 19 shows a second step in the progress of expansion of the expandable member;

Figure 20 illustrates an expandable member emplaced in a bone hole and an insertion element in its full frontward position just after axial release from holding means;

Figure 21 is a cross-section of one type of holding means adapted for use with an insertion element in the shape of a rivet;

Figure 22 is a cross-section of another embodiment of the rivet of Figure 21;

Figure 23 is an exploded view of one embodiment of an emplacement apparatus of the invention;

Figure 24 is an exploded view of another embodiment of an emplacement apparatus of the invention;

Figure 25 is a cross-section of another embodiment of an expandable member and holding means of the invention;

Fig. 1' is a side view, partially cut away and partially in section, of a suture grasping device formed in accordance with the present invention, wherein the rod is shown in its aforementioned proximalmost position;

Fig. 2' is a side view, partially cut away and partially in section, of the device shown in Fig. 1' wherein the rod is shown in its aforementioned distalmost position;

Fig. 3' is an illustrative side view, partially cut away, showing a piece of tissue in phantom, a length of suture and the distal portion of the shaft of a suture grasping device formed in accordance with the present invention, wherein the length of suture is located on one side of the tissue and the distal

portion of the shaft is located on the other side of the tissue, and further wherein the two wire-like elements of the suture grasping device are shown in their retracted position;

Fig. 4' is an illustrative side view similar to that of Fig. 3' except that the shaft is shown extending through the tissue, and the two wire-like elements are located in their fully extended, flared configuration flanking the length of suture;

Fig. 5' is an illustrative side view similar to that of Fig. 4' except that the two wire-like elements have been partially retracted into the distal portion of the shaft so as to snare the suture;

Fig. 6' is an illustrative side view similar to that of Fig. 5' except that the two wire-like elements have been fully retracted into the distal portion of the shaft so as to grasp the suture to the distal portion of the shaft;

Fig. 7' is an illustrative side view, partially cut away and partially in section, showing the distal portion of the shaft of Fig. 6' with the two wire-like elements being retracted to their proximalmost position within the shaft and grasping a length of suture to the shaft;

Fig. 8' is an illustrative side view similar to that of Fig. 6' except that the distal portion of the shaft has been withdrawn from the tissue;

Fig. 9' is an illustrative side view similar to that of Fig. 8, except that the two wire-like elements are shown in their fully extended, flared position flanking the suture which has been drawn through the tissue;

Fig. 10' is an illustrative side view similar to that of Fig. 9' except that the distal portion of the shaft is shown fully disengaged from the suture, with the two wire-like elements in their fully retracted position;

Fig. 11' is an illustrative side view, partially cut away, showing a piece of tissue in phantom, a length of suture and the distal portion of the shaft of a suture grasping device formed in accordance with the present invention, wherein the length of suture and the distal portion of the shaft are located on the same side of the tissue, and further wherein the two wire-like elements of

the suture grasping device are shown in their retracted position;

Fig. 12' is an illustrative side view similar to that of Fig. 11' except that the two wire-like elements are shown in their fully extended, flared positions flanking the length of suture;

Fig. 13' is an illustrative side view similar to that of Fig. 12' except that the two wire-like elements have been fully retracted into the distal portion of the shaft so as to grasp the suture to the shaft;

Fig. 14' is an illustrative side view similar to that of Fig. 13' except that the distal portion of the shaft has been forced through the tissue, carrying the suture with it;

Fig. 15' is an illustrative side view similar to that of Fig. 14' except that the two wire-like elements have been positioned in their fully extended, flared positions flanking the suture;

Fig. 16' is an illustrative side view similar to that of Fig. 15' except that the two wire-like elements have been fully retracted back into the distal portion of the shaft, and the shaft has been withdrawn from the tissue, leaving the length of suture extending through the tissue;

Fig. 17' is an illustrative side view similar to that of Fig. 11' except that the tissue comprises two pieces of tissue in side-by-side relation to one another;

Fig. 18' is an illustrative side view similar to that of Fig. 17' except that the two wire-like elements are shown in their fully extended, flared positions flanking the length of suture;

Fig. 19' is an illustrative side view similar to that of Fig. 18' except that the two wire-like elements have been fully retracted into the distal portion of the shaft so as to grasp the suture to the shaft;

Fig. 20' is an illustrative side view similar to that of Fig. 19' except that the distal portion of the shaft has been forced through the tissue, carrying the suture with it;

Fig. 21' is an illustrative side view similar to that of Fig. 20', except

that the two wire-like elements have been positioned in their fully extended, flared positions flanking the suture;

Fig. 22' is an illustrative side view similar to that of Fig. 21' except that the two wire-like elements have been fully retracted back into the distal portion of the shaft, and the shaft has been withdrawn from the tissue, leaving the length of suture extending through the tissue;

Fig. 23' is an illustrative side view similar to that of Fig. 22' except that an additional portion of the suture is shown;

Fig. 24' is an illustrative side view similar to that of Fig. 23', except that the two wire-like elements have been extended to their fully extended, flared positions flanking a portion of the suture extending outwardly from the right hand side of the side-by-side pieces of tissue;

Fig. 25' is an illustrative side view similar to that of Fig. 24', except that the two wire-like elements have been fully retracted into the distal portion of the shaft so as to grasp the suture to the shaft;

Fig. 26' is an illustrative side view similar to that of Fig. 25', except that the distal portion of the shaft has been forced through the tissue a second time, carrying the length of suture with it;

Fig. 27' is an illustrative side view similar to that of Fig. 26', except that the two wire-like elements have been positioned in their fully extended, flared positions flanking the suture;

Fig. 28' is an illustrative side view similar to that of Fig. 27', except that the two wire-like elements have been retracted back into the distal portion of the shaft, and the shaft has been withdrawn from the tissue, so as to leave the length of suture extending from left to right through the tissue at a first location and extending from right to left through the tissue at a second location;

Fig. 29' is an illustrative side view similar to that of Fig. 28', except that the shaft extends left to right through the tissue at a third location, and wherein the two wire-like elements are located in their fully extended, flared positions flanking one of the free ends of the length of suture located on the left

side of the tissue;

Fig. 30' is an illustrative side view similar to that of Fig. 29', except that the two wire-like elements have been moved to their fully retracted position so as to grasp one of the free ends of suture on the left side of the tissue to the shaft;

Fig. 31' is an illustrative side view similar to that of Fig. 30', except that the distal portion of the shaft has been withdrawn from the tissue, carrying a free end of the suture with it;

Fig. 32' is an illustrative side view similar to that of Fig. 31', except that the two wire-like elements have been positioned in their fully extended, flared positions flanking the length of suture;

Fig. 33' a side view, partially cut away and partially in section, showing a second embodiment of the present invention, wherein the actuation means are positioned so as to place the two wire-like elements in their retracted position;

Fig. 34' is a view similar to that of Fig. 33', except that the actuation means are positioned so as to place the two wire-like elements in their fully extended, flared position;

Fig. 35' is a side view in partial section showing a grasper assembly formed in accordance with the present invention, wherein the grasper device is the same as that shown in Figs. 33' and 34';

Fig. 36' is an exploded view of the grasper assembly shown in Fig. 35';

Fig. 37' is a side view of a wire subassembly suitable for use in the grasper assembly shown in Fig. 35';

Fig. 38' is a top view of the wire subassembly shown in Fig. 37';

Fig. 39' is a side view, partially in section, of a shaft subassembly suitable for use in the grasper assembly shown in Fig. 35';

Fig. 40' is a side view of a shaft bearing suitable for use in the grasper assembly shown in Fig. 35';

Fig. 41' is a left end view of the shaft bearing shown in Fig. 40';

Fig. 42' is a right end view of the shaft bearing shown in Fig. 40';

Fig. 43' is a side view of an outer housing suitable for use in the grasper assembly shown in Fig. 35';

Fig. 44' is a left end view of the outer housing shown in Fig. 43';

Fig. 45' is a right end view of the outer housing shown in Fig. 43';

Fig. 46' is a side view in section of the outer housing shown in Fig. 43';

Fig. 47' is a side view of an inner housing suitable for use in the grasper assembly shown in Fig. 35';

Fig. 48' is a left end view of the inner housing shown in Fig. 47';

Fig. 49' is a right end view of the inner housing shown in Fig. 47';

Fig. 50' is a bottom view of the inner housing shown in Fig. 47';

Fig. 51' is a side view of a gear suitable for use in the grasper assembly shown in Fig. 35';

Fig. 52' is an end view of the gear shown in Fig. 51';

Fig. 53' is a side view of an end cap suitable for use in the grasper assembly shown in Fig. 35';

Fig. 54' is a left end view of the end cap shown in Fig. 53';

Fig. 55' is a side view of a lock nut suitable for use in the grasper assembly shown in Fig. 35';

Fig. 56' is a left end view of the lock nut shown in Fig. 55';

Fig. 57' is a right end view of the lock nut shown in Fig. 55';

Fig. 58' is a sectional view of the distal end of the shaft;

Fig. 59' is a sectional view of the distal end of an alternative form of the shaft;

Fig. 60' is a side view of the distal end of another form of suture grasping device, wherein the device comprises just one hooked wire-like element;

Fig. 61' is a side view of the distal end of yet another form of suture grasping device, wherein the device comprises a pair of hooked wire-like elements;

Fig. 62' is a side view of the distal end of still another form of suture

grasping device, wherein the device comprises a pair of hooked wire-like elements and further wherein the hooks are formed so that they overlap one another;

Fig. 63' is a side view of the distal end of yet another form of suture grasping device, wherein the device comprises a pair of hooked wire-like elements, and further wherein the hooks are formed so that the hook of one wire-like element will reside within a projection of the hook of the other wire-like element; and;

Fig. 64' is a side view of the distal end of still another form of suture grasping device, wherein the ends of the two wire-like elements include ball-like enlargements.

Fig. 1'' is a side elevation of a preferred embodiment of the invention constituting a surgical scissors designed for laparoscopic surgery;

Fig. 2'' is a side view in elevation of the left hand half of the handle housing;

Fig. 3'' is a side view in elevation of the right hand half of the handle housing;

Fig. 4'' is a front view in elevation of the handle part shown in Fig. 3'';

Fig. 5'' is a side elevation of the insulator housing;

Fig. 6'' is a sectional view in side elevation of the insulator housing taken along its center line;

Fig. 7'' is a rear end view of the insulator housing; Fig. 8'' is a front end view in elevation of a cap for the insulator housing;

Fig. 9'' is a side view in elevation of the end cap of Fig. 8'';

Fig. 10'' is a fragmentary longitudinal sectional view in side elevation showing the handle assembly without the right hand half of the handle housing;

Fig. 11'' is a plan view of a rod to which the tool head is connected;

Fig. 12'' is a side view showing the rod of Fig. 11'' rotated 90° on its axis;

Fig. 13'' is a side view of a helical gear that is affixed to the rod of Fig.

11'';

Fig. 14'' is an end view of the gear of Fig. 13''; Fig. 15'' is a cross-sectional view taken along line 15''-15'' of Fig. 1'';

Fig. 16'' is a cross-sectional view along line 16''-16'' of Fig. 1'';

Fig. 17'' is a cross-sectional view taken along line 17''-17'' of Fig. 1'';

Fig. 18'' is a side view in elevation of the tube housing;

Fig. 19'' is a longitudinal sectional view in elevation of the tube housing;

Fig. 20'' is a bottom plan view of the tube housing; Fig. 21'' is a front end view of the tube housing; Fig. 22'' is an enlarged cross-sectional view of a portion of the tool head drive assembly;

Fig. 23'' is a cross-sectional view taken along line 23''-23'' of Fig. 22'';

Fig. 24'' is a cross-sectional view taken along line 24''-24'' of Fig. 22'';

Fig. 25'' is a side elevation of the operating trigger member;

Fig. 26'' is a front end view in elevation of the trigger member of Fig. 25'';

Fig. 27'' is a side view in elevation of the rotational trigger member;

Fig. 28'' is an exploded view showing how the tool head is detachable from its supporting rod;

Fig. 29'' is a top plan view of one of the scissors blade members;

Fig. 30'' is a top plan view of the tool (scissors) head in open position;

Fig. 31'' is a fragmentary sectional view showing inclusion of a spring for holding the trigger member in its forward position;

Fig. 32'' is a side elevational view of a surgical instrument formed in accordance with the present invention having a novel tool head designed to facilitate suture throw rundown toward a surgical site;

Fig. 33'' is an enlarged side view, partially cut away and partially in section, showing the novel tool head of Fig. 32'' in its open position;

Fig. 34'' is an enlarged side view, partially cut away and partially in section, showing the novel tool head of Fig. 32'' in its closed position;

Fig. 35'' is an enlarged side view, partially cut away, showing the novel tool head of Fig. 32'' in its closed position and with the internal structure of the surgical throw rundown assembly shown in phantom;

Fig. 36'' is a distal end view of the novel tool head of Fig. 35'';

Fig. 37'' is a side elevational view of the lower one of the two tool head members shown in Fig. 33'', with the member being shown at an intermediate stage of manufacture before it has been bent into the shape shown in Fig. 33'';

Fig. 38'' is a bottom view of the tool head member shown in Fig. 37'';

Fig. 39'' is a distal end view of the tool head member shown in Fig. 37'';

Fig. 40'' is a side elevational view of the upper one of the two tool head members shown in Fig. 33'', with the member being shown at an intermediate stage of manufacture before it has been bent into the shape shown in Fig. 33'';

Fig. 41'' is a top view of the tool head member shown in Fig. 40'';

Fig. 42'' is a distal end view of the tool head member shown in Fig. 40'';

Fig. 43'' is an illustrative view showing two suture ends extending away from a surgical site, with a surgical throw being formed in the suture ends at a location spaced from the surgical site;

Fig. 44'' is a view similar to that of Fig. 43'', but showing one of the suture ends threaded through one of the tool head members;

Fig. 45'' is a view similar to that of Fig. 44'', but showing the other suture end threaded through the other one of the tool head members, and with the two tool head members being shown in their closed position;

Fig. 46'' is a view similar to that of Fig. 45'', but showing the novel tool head having run the surgical throw down to the surgical site;

Fig. 47'' is a view similar to that of Fig. 46'', but showing the two tool head members in their open position;

Fig. 48'' is a view similar to that of Fig. 47'', but showing the novel tool head about to cut off the suture ends extending away from a knot which

has been formed at the surgical site; and

Fig. 49'' is a view similar to that of Fig. 48'', but showing the novel tool head after cutting of the suture ends extending away from the knot formed at the surgical site.

Detailed Description of the Invention

The Bone Fastener

The bone fastener, for use in the invention, generally includes an elongated insertion element and an approximately cylindrical expandable member with an axial channel for receiving the insertion element. In its unexpended state, the expandable member can be placed into a pre-drilled opening in a bone. A diameter of at least a portion of the insertion element is greater than that of at least a portion of the axial channel so that, when the element is inserted into the axial channel, the wider portion of the insertion element is forced outward against the axial channel. The axial channel is susceptible to enlargement by this force acting substantially orthogonal to the axial channel. This outward force causes the expandable member to expand ineversibly against the wall of the opening, fixing the insertion element within the expandable member and fixing the expandable member in a pressure fit firmly within the opening. As described in more detail below, the insertion element or the expandable member, or both of them, can be adapted to provide a fastener for attaching soft tissue using a suture or to provide a rivet for attachment without a suture.

A. The Expandable Member

An embodiment of the expandable member 10 of the present invention is illustrated in Figure 1. The expandable member is a substantially cylindrical body having one and another ends; a proximal end 12 that first enters the bone opening and a distal end 14 farthest away from the proximal end. The expandable member is preferably constructed of a biocompatible material that

is sufficiently deformable so that, when expanded within a bone opening, the member will conform to a substantial degree with the irregularities in the bone opening wall. The term "biocompatible" means that the expandable member material is chemically and biologically inert. Suitable materials for the expandable member include, for example, an implant grade high density polyethylene, low density polyethylene (PE 6010 and PE 2030) and polypropylene (13R9A and 23M2: all made by Rexene, Dallas, Texas). Of these, PE 6010 and 13R9A have been FDA listed as class 6 materials.

The expandable member may also be bioabsorbable. The term "bioabsorbable" refers to those materials that are meant to be decomposed or degraded by bodily fluids, such as, for example, blood and lymph. The expandable member is preferably made from a biodegradable polymer or copolymer of a type selected in accordance with the desired degradation time. That time in turn depends upon the anticipated healing time of the tissue which is the subject of the surgical procedure. Known bioabsorbable polymers and copolymers range in degradation time from about 3 months for polyglycolide to about 48 months for polyglutamic-co-leucine. A common bioabsorbable polymer used in absorbable sutures is poly (L-lactide) which has a degradation time of about 12 to 18 months. The preferred expandable member is comprised of an absorbable copolymer derived from glycolic and lactic acids, such as a synthetic polyester chemically similar to other commercially available glycolide and lactide copolymers. Glycolide and lactide degrade and absorb in the body by hydrolysis into lactic acid and glycolic acid which are then metabolized by the body. The following Table set forth below lists polymers which are useful for the bioabsorbable material employed for the expandable member, and other parts of the bone fastener as described below. These polymers are all biodegradable into water-soluble, non-toxic materials which can be eliminated by the body. Their safety has been demonstrated and they are listed as approved materials by the U.S. Food and Drug Administration.

TABLE

Polycaprolactone
Poly (L-lactide)
Poly (DL-lactide)
Polyglycolide
95:5 Poly (DL-lactide-co-glycolide)
90:10 Poly (DL-lactide-co-glycolide)
85:15 Poly (DL-lactide-co-glycolide)
75:25 Poly (DL-lactide-co-glycolide)
50:50 Poly (DL-lactide-co-glycolide)
90:10 Poly (DL-lactide-co-caprolactone)
75:25 Poly (DL-lactide-co-caprolactone)
50:50 Poly (DL-lactide-co-caprolactone)
Polydioxanone
Polyesteramides
Copolyoxalates
Polycarbonates
Poly (glutamic-co-leucine)

Referring to Figure 1, the expandable member 10 includes an outer surface 13 for secured engagement with an inner surface of a bone opening. Outer surface 13 can be smooth or can be provided with a plurality of ridges 16 as shown. In particular, a preferred configuration includes a plurality of annular ridges for engaging irregularities in the bone opening wall as the expandable member 10 deforms and conforms to the bone opening wall during and after expansion. It will be appreciated that ridges 16 may also be axially aligned with the long axis (shown by arrow A in Figure 1) of the expandable member. The shape and design of the outer surface ridges 16 are not intended to limit the scope of the invention in any way.

The ability of the expandable member to conform to the inner

dimensions of a bone opening may be augmented considerably by providing the outer surface of the expandable member with one or more slots (not shown) extending between the proximal and distal ends of the expandable member, the ends of the slots disposed at some distance remote from the proximal and distal ends of the expandable member. That is, the ends of the slots are not in contact with the ends of the expandable member. The slots allow the member to flex and conform to irregularities in the bone hole. The slots may be run axially or circumferentially along the outer surface of the expandable member.

An axial channel 18 is defined between the ends 12, 14 of the expandable member 10 and preferably extends completely through the expandable member. The axial channel 18 has a certain inner diameter, indicated by reference letter D in Figure 1. The diameter may be substantially constant along the longitudinal axis (A) of the axial channel 18, although the diameter may also vary along one or more portions of the length of the channel. In one embodiment, (illustrated below in Figure 9) one or more steps 20 are defined in the inner surface 19 of the axial channel 18. These steps are designed to mate with corresponding ridges on the outer surface of an insertion element (see below).

Referring again to Fig. 1, one end of the expandable member, (i.e. the proximal end 12) is specially adapted for insertion into the bone opening. This end is always of a diameter smaller than the inside diameter of the bone opening. The proximal end 12 of the expandable member 10 may include a substantially flat portion 21 for engagement with an outer surface of an insertion element (see Figure 8).

The expandable member 10 may also be adapted to form a rivet for directly affixing soft tissue, or an object such as a bone plate, to the bone at the fixation site. Figure 2 shows an example of such a rivet 22, in which the distal end 14 of the expandable member is configured to form a radial projection 23. In Figure 2, the projection is formed as a flange 24. The proximal surface 25 of flange 24 is generally planar and perpendicular to the longitudinal axis (A)

of the member 10. The distal surface 26 of flange 24 is contoured to provide a smooth, generally dome shaped head, thinner near the margin than toward the center.

Figure 3 illustrates a rivet-type expandable member 10 placed in a bone opening. The member 10 has a distal end 14 configured to form a radial projection 23 and a stand-off 28. The stand-off 28 is disposed between the radial projection 23 and a bone surface 29. The member 10 may have on its outer surface 13 a series of ridges 16 over an area that is to contact a bone opening wall 30 and a smooth section 31 over an area between the ridges 16 and the radial projection 23. The outer surface 13 of the expandable member 10 may also be provided with a stop 32 extending substantially orthogonal to the outer surface 13 of the member. Stop 32 is provided at the junction between the stand-off 28 and that portion of the outer surface 13 that contacts the bone wall 30 to limit precisely the depth to which the expandable member is inserted into the bone opening 33. In the embodiment illustrated, this stop 32 is formed as a pair of substantially rectangular protrusions, extending far enough out from the outer surface 13 of the member so that the protrusions contact the bone surface 29 at an edge 17 of the bone opening 33, stopping the frontward progress of the expandable member 10. When the operator senses the contact of the stop with the bone surface, a mechanism for inserting an insertion element can be activated, thus effecting fixation of the expendable member at the pre-determined depth. Stand-off fasteners can be dimensioned to provide for various insertion depth and stand-offs, according to the particular surgical setting.

Figures 1-3 also illustrate a feature of the invention common to many embodiments of the expandable member; namely a structure 15 for axially releasing the expandable member from a holder device (not shown). The structure, described in more detail below, is preferably a membrane that is broken during emplacement of the bone fastener in a bone opening. The membrane is broken by a substantially continuous, non-impact force in a

direction parallel to (i.e., axial to) the longitudinal axis of the expandable member. Structure 15 is disposed at a distal end of the expandable member 10 and is represented in Figure 3 as a jagged, distal edge of projection 23. This is, when fully emplaced in a bone opening 33, the expandable member may retain a portion of the previously intact, axially releasing structure 15.

In other embodiments, not illustrated here, the outer surface of the expandable member can include self-tapping screw threads for engagement with the inner surface of the bone opening. The screw threads provide for positioning of the expandable member in the hole at its desired depth or for applying a desired force upon the object between a radial projection of the expandable member and the bone surface, prior to fixation by forcing the insertion element into the axial channel of the expandable member. In such a turnable screw thread configuration, the unexpended member can be turned into a bone hole having a diameter somewhat smaller than the outside diameter of the screw threads, so that the screw threads self-tap the hole to some extent as the member is turned into the hole. Although the threads are not meant to tap the bone hole to an extent sufficient by themselves to effect fixation of the member, surfaces of the screw threads can be hardened sufficiently to cut or abrade the bone hole wall. Such hardening can be provided, for example, by forming the member of a relatively deformable polymer material that can be hardened by application of heat or radiation, and then irradiating selective parts of the member outer surface to harden it at those parts. Ultimately, the softer material of the member can be provided over selective parts of its surface with a thin coating of a harder more durable material. Once such a self-tapping member has been turned into the bone hole to the desired depth, an insertion element can be forced into the axial channel of the member, expanding it and deforming the outer surface thereof as described above.

The expandable member may be fabricated by conventional molding or extrusion procedures and the sizes can vary over a wide range depending upon the particular surgical procedure. An exempla y expandable member can be

about 0.40 inches (10.1 mm) long, with an outside diameter of about 0.140 inches (3.5 mm), the proximal opening of the axial channel being tapered to about 0.07 inches (1.7 mm).

B. The Insertion Element

Figure 4 illustrates in diagrammatic cross-section an insertion element 34 of the present invention. The insertion element 34 is a substantially elongated shape having distal 35 and proximal 36 ends, and an outer surface 37. The outer surface, most preferably at one end, has a projection 38 for engagement with inner surface 19 of the axial channel 18 of expandable member 10 (see Figure 1). Insertion element 34 may be constructed of a relatively hard biocompatible material such that the projection 38 expands the expandable member outwardly in a direction substantially orthogonal to the longitudinal axis of the expandable member. It will be appreciated that the projection 38 on the outer surface 37 of insertion element 34 can include a variety of configurations and designs. These configurations are not intended to limit the scope of the invention in any way.

A channel 40 is defined between ends 35,36 of the insertion element. The channel is adapted to engage a suture. In the embodiment illustrated, channel 40 extends completely between the opposed ends 35, 36 of insertion element 34. The insertion element at one of its ends, preferably the proximal end 36, includes a structure for attaching a suture. As illustrated in Figure 7 below, the structure is most preferably an outer, flattened, peripheral wall 43 of insertion element 34. This outer wall is of sufficient width to engage a knot 44. Other means for attaching a suture may include, for example, one or more slots disposed at an end of the insertion element for trapping the knotted free ends of the suture within the jaws of the slot(s). Further, a suture attaching means can include a variety of clips or other devices.

The embodiment of Figure 5 shows insertion element 34 provided with a channel to receive an intermediate portion of a suture (i.e., a segment

between the free ends) to form a so-called "slidable"suture element. Insertion element 34 has a generally cylindrical shaft 52 provided with an expanded distal portion 48. A channel 50 is defined through the shaft 52 in a direction substantially at right angles to the longitudinal axis (A) of the shaft and may be located anywhere along the shaft. Preferably, the channel 50 is defined at, or adjacent to, the distal end 35 of the shaft 52. One or more projections 38 are provided for engaging the inner surface 19 of the expandable member's axial channel 18 (see Figure 1). An intermediate portion of a suture thread may be engaged within channel 50. The expanded portion 48 at the distal end 35 of shaft 52 may be provided with a plurality of grooves, not shown. These grooves have a diameter sufficient to receive the suture thread, thus allowing the suture thread to lie flat and substantially parallel to the longitudinal axis of the insertion element without protruding.

Figure 10 illustrates the elongated, slidable suture insertion element of Figure 5 in place within expandable element 10 in bone opening 33. All reference numbers are identical to those shown previously. This particular fastener is designed to engage an intermediate portion 47 of suture 46.

Another embodiment of an insertion element of the present invention is provided in Figure 6 which shows an insertion element 34 in the shape of a rivet 58. This rivet is for coupling an object to bone for use with the expandable member of the invention. Rivet 58 is an elongated element for insertion into the axial channel 18 of expandable member 10 (see Figure 1), the rivet having a shaft 52 with distal and proximal ends 35, 36, respectively. Rivet 58 may have a channel 40 defined between the ends. A radial projecting portion 60 is provided at the distal end 35.

A washer 62 having an annular bore 64 may additionally be provided to enclose a portion of the shaft 52. The washer has upper 63 and lower 65 surfaces and bore 64 is defined between these surfaces as a single opening. The shaft 52 of the rivet is inserted within the bore.

The upper surface 63 of washer 62 is in facing relationship, and may be

engaged with a lower surface 66 of the radial projection 60. Preferably, as shown in Figure 6, the lower surface 65 of the washer includes a series of spaced-apart projections 67 extending away from the radial projection 60 and toward the proximal end 36 of the rivet. Spaced-apart projections 67, which may be of variable length, are intended to be inserted directly into the bone or into tissue distal to the bone and provide a grasping surface for the washer. The height of spaced-apart projections 67 provides sufficient distance between the washer and tissue so that the tissue will not undergo necrosis by being compressed too tightly by the washer or projection 60.

Most preferably, the outer diameter of the radial projection 60 is greater than the diameter of annular bore 64 of washer 62 which diameter, in turn, is greater than the outer diameter of rivet shaft 52. Thus, the bore of the washer is sufficiently large so that the washer can slide underneath the projection 60 of the rivet 58. This also provides sufficient distance between tissue and rivet to eliminate or substantially suppress tissue necrosis (see also Figure 11). Moreover, the upper surface 63 of washer 62 and the lower surface 66 of radial projection 60 have a different radii of curvature. This differential radii of curvature allows the rivet to "float" between the tissue and the washer. It therefore allows the rivet to move relative to the washer to account for different orientations and angles of the bone surface.

Figure 11 illustrates an insertion element rivet 58 and washer 62 of Figure 6. The rivet is in place within expandable element 10 in bone opening 33. Figure 11 also illustrates how projections 67 are inserted into tissue 68 and bone 69 to provide a grasping surface for the washer 62. All other reference numbers are as previously disclosed. Figure 11 particularly illustrates the floating nature of rivet 58 within its captured washer 62, allowing insertion in the bone at angles other than exactly orthogonal to the tissue and/or bone surface.

In further embodiments, one or both of the washer surfaces 63, 65 may include a means for enhancing tissue proliferation on the washer after it is

inserted into the tissue and bone opening. This means for enhancing tissue proliferation can include a plurality of small apertures (not shown in Fig. 6) defined between the upper and lower surfaces 63, 65 of the washer 62, these apertures disposed on a peripheral portion of the upper and lower surfaces. Further, tissue proliferation can be enhanced by including one or more roughened portions (not illustrated) on either, or both, of the upper and lower surfaces of the washer. The washer and/or insertion member could also be coated or impregnated with a variety of bone and tissue growth enhancing factors such as, for example, hydroxyapatite, calcium phosphate, and the like. Preferably, the washer is made of a bioabsorbable material identical to those described above. The chemical composition of the washer may be chosen so that it will be absorbed completely once the tissue fixed by the rivet has reattached itself to the bone. Moreover, the insertion element may also comprise a bioabsorbable material, as described above with regard to the expandable element.

A significant advantage of the rivet configurations of the present invention is that the operator can set the compressive force between tissue, fastener, and bone by manually adjusting the pressure of the rivet against the tissue at the time the tissue is being fastened. .

Figure 7 illustrates in a less diagrammatic cross-sectional view, a suture fastener 11 of the invention emplaced in a pre-drilled hole 33 in bone. Figure 7 shows deformation of the outer portion of expandable member 10 within irregularities in the bone hole wall. This deformation results from the forcible expansion of the expandable member within the bone hole and has two major effects: (i) the density of the bone surrounding the expandable member is increased by the forces exerted upon the bone and (ii) a bulge is created underneath the outer bone surface causing interference between the insertion element and the exit diameter of the bone hole.

The insertion element 34 has been compressed into the axial channel 18 of an expandable member 10, the proximal projection 38 of the insertion

element 34 expanding the member's outer surfaces 13 thereof against the wall 30 of the bone hole 33. The term "compressed" refers to a force lacking impact or impulse. The suture 46, which can be, for example, a standard braided dacron suture, is knotted against the proximal end 36 of insertion element 34, passes through axial channel 40 and out of the fastener 11 where it can be used to attach soft tissue to the bone at the fixation site. The severed axial releasing structure 15 is also illustrated at distal end 14 of expandable member 10. Figure 8 illustrates an embodiment in which proximal projection 38 is placed so that it extends out of the proximal end 12 of expandable member 10. In this configuration, a shoulder 168 of proximal projection 38 engages flat portion 21 at the proximal end 12 of the expandable member 10. All reference numbers are identical to those presented above. This engagement provides added security to the bone fastener to prevent the insertion element from backing out of the expandable member.

Figure 9 illustrates a further embodiment in which a step 20 is defined in the inner surface 19 of axial channel 18. The step is adapted to mate with a corresponding ridge 39 on the outer surface of insertion element 34. Alternate embodiments may include a plurality of steps and ridges as well. All reference numbers are identical to those presented previously.

The insertion element mates with the axial channel of the expandable member. Accordingly, its size may also vary over wide limits. Exemplary insertion elements designed to mate with the expandable members described previously are about 0.44 inches (11.1 mm) long with a channel diameter of about 0.060 inches (1.5 mm). The rivet type insertion element (see Figure 6) has a distal radial projection about 0.180 inches (4.6 mm) wide, with a total length of about 0.5 inch (12.7 mm). An exemplary slidable suture element (see Figure 5) is about 0.47 inches (11.9 mm) long, with a distal bore about 0.05 inches (1.3 mm) across and 0.04 inches (1.0 mm) deep. An exemplary washer designed to mate with the rivet of Figure 6, is about 0.29 inches wide, with a central bore about 0.14 inch (3.5 mm)". A total of six projections may

be equally spaced around the lower washer surface, each projection about 0.065 inches (1.6 mm) long.

C. Holding Means

Figure 12 shows emplacement of member 10 within bone hole 33 using a preferred holding means 70 which is adapted to provide for firm deployment of the fastener without imposing substantial forces upon the bone itself in directions toward or away from the bone. In Figure 12, expandable member 10 having axial channel 18 and outer surface 13 is shown in an unexpended state at which the axial channel 18 has a diameter (**a**) and the outer surface 13 has a diameter (**b**) at its widest point or points. Diameter (**b**) may be equal to the diameter (**c**) of the bone hole so that expandable member in an unexpended state passes into a hole in a light, press-fit configuration. The holding means 70 is an elongated, substantially hollow tube 71 having an inside diameter (**d**) greater than the outside diameter (**e**) of distal end 14 of expandable member 10.

The proximal end 72 of holding means 70 is integral with the distal end 14 of the expandable member 10. The term "integral" refers to a variety of configurations in which the proximal end of the holding means is in physical communication with the distal end of the expandable member. The term "integral" refers to units made of one piece of material as well as components which may be separate initially but are later joined to form a complete device. In the embodiment of Fig. 12, this physical linkage may be via a continuous, unbroken surface 73 extending between the holding means 70 and expandable member 10.

Nevertheless, a single, continuous surface is not necessary between holding means 70 and member 10. Expandable member 10 may be snap-or press-fit into position at the proximal end of holding means 70 using a variety of mechanisms. Referring to Figure 13, the proximal end of expandable member 10 is press-fit into a bore 71 defined at proximal end 72 of holding

means 70. The expandable member 10 may include one or more detents 74 adapted to engage with corresponding surfaces 76 on the holding means 70.

Figure 14 illustrates a two-piece holding means 70 having an intermediate end 72 supplied with a series of screw threads 75. A corresponding series of screw threads 78, designed to mate with threads 75, are disposed at a second, intermediate end 73.

Figure 25 illustrates another way of integrating the proximal end of holding means 70 with expandable member 10. As illustrated, proximal end 72 of holding means 70 is provided with a bore 71 having surfaces 76 designed to mate with corresponding detents 74 on expandable member 10 in a manner allowing expandable member 10 to be spun onto holding means 70 or crimped onto holding means 70. All other reference numbers are as described previously. Thus, in Figures 12-14 and 25, the expandable member 10 is constructed to allow the holding means 70 to maintain engagement with the expandable member during the steps of emplacement in the bone.

Moreover, each of the embodiments of Figures 12-14 and 25 includes a structure for axially releasing the expandable member from the holding means. The manner of activating the axial releasing structure is described below but it will be appreciated that the structure may be arranged as a substantially annular ring or membrane of material. In Figures 12-14 and 25, axial releasing structure is a frangible membrane 84. The term "frangible" refers to a membrane that is breakable or fragile. In particular, Figure 12 illustrates frangible membrane 84 as an annular attachment portion connecting holding means 70 and expandable member 10. Figure 13 illustrates frangible membrane 84 connected the distal end of expandable member 10 to a detent 74, the membrane between detent 74 and member 10 severable during emplacement of the fastener, as described below. Figure 14 illustrates frangible membrane 84 disposed between distal end 14 of the expandable member 10 and a threaded portion 75 of holding means 70. The axial releasing structure, however, may be other than a complete annulus of frangible material. In Figure 15, the

membrane 84 is a series of spokes or webbing 85. In this configuration, only the spokes need be broken. Alternately, as shown in Figure 16, the structure for axially releasing the expandable member is a plurality of very attenuated membranes 86.

An exemplary holding means may have a diameter of between about 0.070 - 0.140 inches (1.7 - 3.5 mm) and is integral with the expandable member (see Figure 12) by way of an annular frangible membrane about 0.01 - 0.02 inches (.25 - .50 mm) thick.

D. Methods

One method, although by no means the only method, for attaching soft tissue to bone will be described below with reference to the rivet fastener of the present invention. To attach soft tissue to bone, a surgeon takes the sharpened proximal end of a K-wire (manufactured, for example, by Kirschner Medical Company) and spears the tissue that is to be attached. The proximal end of the K-wire is then placed over the bone surface at the approximate site of attachment. The K-wire is then drilled into the bone at that site. If the location is where the surgeon wants it, the surgeon then threads a cannulated drill of the appropriate size over the K-wire. A hole is then drilled into the bone using the cannulated drill. Then drill is then removed, leaving the K-wire in place. The rivet of the invention is then loaded into an expandable member contained within an emplacement apparatus (described below with reference to Figures 23 and 24). The rivet is run over the K-wire and the expandable member pressed downwards through the tissue and into the bone hole so that the expandable member is emplaced into the bone hole. If the surgeon decides that the orientation of the bone fastener and soft tissue is correct, the emplacement apparatus is triggered to set the bone fastener within the bone hole. The emplacement apparatus and then the K-wire are removed in turn. Other variations on this technique include first drilling a bone hole and then punching a hole through the soft tissue. The tissue is then moved over the bone hole

using, for example, a K-wire or a grasping device. The K-wire is inserted into the hole in the soft tissue and bone and then the emplacement apparatus of the invention is threaded over the K-wire.

The preferred method includes providing an expandable member for insertion into an opening in the bone, the member having defined in it an axial channel with a certain diameter, as described above. The expandable member includes a structure for axially releasing it from a holding means. The expandable member is grasped at the distal end using the elongated holding means described previously. The expandable member is inserted into a bone opening with the holding means while maintaining contact with the distal end of the expandable member. A compressive force, which may be continuous, is applied to the expandable member in order to expand the diameter of the axial channel so that an outer surface of the expandable member engages the bone. The force is applied by compressing the elongated insertion element into the axial channel of the expandable member. The projecting portion at an outer surface of the insertion element is engaged with the inner surface of the axial channel of the expandable member to exert a force substantially orthogonal to the axial channel. The diameter of the axial channel expands within the bone opening as the projecting portion travels proximately within the axial channel. The means for axially severing the expandable member is then activated, so that the expandable member, fully expanded into the bone opening by the inserted element, is released from the holding means when the continuous, compressive force stops. In particular, when the frangible membrane is axially severed, the expandable member is disengaged from its holding means.

It is an important feature of the present invention that the force needed to expand the expandable member may be substantially continuous and spread out over time so that the force is not an impulse, as in prior art methods. The expandable member is expanded using the insertible element with a compressive motion that is axially delivered in a direction substantially parallel to the longitudinal axis of the insertion element. Thus, the apparatus for inserting a

bone fastener requires an advancing drive mechanism which lacks any impact or impulse characteristics. In physical terms, it can be considered that the system of: (i) a bone; (ii) a K-wire to guide a drill to make an opening in the bone; (iii) a bone fastener emplaced over the K-wire in the opening; and (iv) an apparatus for emplacing the bone fastener, comprises a closed, continuous boundary system in which no external forces are applied to the system such as, for example, by a hammer or impactor.

Figure 17 shows emplacement of a bone fastener 11 within a bone hole 33 using an apparatus of the present invention. The bone surface is indicated as reference number 29. Insertion element 34 has at least one projection 38 in facing relationship to a beveled portion 88 along inner surface 19 of axial channel 18. A plunger 90 surrounded by a releasing element 92 (not shown in Figure 17) is directed from a first position, where the plunger is remote from insertion element 34, to a second position, where the plunger is engaged with the distal end 35 of insertion element 34. The plunger and releasing element 92 are coaxially aligned within hollow tube 71 of holding means 70. The plunger 90 is then further urged forward, pressing insertion element 34 before it into the axial channel 18 of the expandable element 10.

Figures 18 and 19 show the progress of expansion of member 10 as the proximal projection 38 of insertion element 34 presses outward against the inner surface 19 of axial channel 18. In Figures 18 and 19, releasing element 92 is shown with a proximal shearing surface 93 which may be a beveled blade. Any proximal surface sufficient to shear the frangible membrane would be sufficient. Also illustrated in Figures 18-19 is a suture 46 whose knot 44 is engaged with the suture attachment means 42 at the proximal end of the insertion element 34.

Insertion element 34 is forced frontward to its full extent as shown in Figure 19. As insertion element 34 approaches its full frontward position, the surface 93 of releasing element 92 approaches, then meets, and then passes through the structure for axially releasing expandable member 10 (e.g.,

frangible membrane 84), severing the expandable member 10 from the hollow holding means 70, and thereby freeing the fully expanded and firmly fixed fastener 11 from means 70. It will be appreciated that element 92 may have a completely annular distal surface 93 to coincide with the annular structure of the frangible membrane 84 illustrated above. If the frangible membrane 84 includes a series of discontinuities, as illustrated above in Figures 15-16, then the releasing element 92 can have shearing surfaces that are also discontinuous.

The holding means 70 is then withdrawn from the site, leaving the fastener in place at the fixation site in the bone.

Alternately, the frangible membrane 84 may be severed without using a releasing element. One embodiment of the invention relies on the inherent resiliency of the frangible membrane and the failure of the membrane during tension and elongation. Referring now to Figure 20, an expandable member 10 is shown emplaced in a bone hole and an insertion element 34 in its full frontward position just after axial release from holding means 70. If the bone hole 33 is of a depth (E) that is substantially identical to the length of the expandable member 10, a force (solid arrow X) will be exerted on membrane 84 in a direction substantially parallel to the longitudinal axis of the expandable member (double-headed arrow Y) but in a direction opposite the compressive force (solid arrow Z) exerted by the plunger 90 in its coaxial travel within the hollow tube 71 of holding means 70. It will be appreciated that the magnitude of compressive force Z is substantially equal in magnitude and opposite in direction to force X. Forces X and Z will activate the axial releasing structure (e.g., the frangible membrane 84) by forcing it to elongate and stretch in the same direction. At a certain point, when force X is greater than the strength of frangible membrane 84, the membrane 84 will fail, thus releasing the expandable member and insertion element from the holding means. Suture 46 and knot 44 are also illustrated. This type of releasing mechanism is dependent on the physical properties of the frangible membrane and the rate of shear.

The same forces can be obtained by providing the insertion element as a rivet 58 as illustrated in Figure 6. In this case, plunger 90 engages the radial projection 23 of the rivet 58 which is stopped against the bone surface. This engagement provides the forces necessary to elongate and stretch the frangible membrane to its breaking point. With regard to embodiments in which the frangible membrane 84 includes a series of attenuated membranes (see Figures 15 and 16), the front-to-rear dimension of each of the membranes is sufficiently thick so that it can withstand the counterforce required to balance the force of urging the insertion element into the axial channel of the expandable member. But the connection of the frangible membrane to the expandable member is thin enough so that, with the insertion element fully inserted and the expandable member affixed in the bone hole, the emplacement means can be rotated about its long axis as indicated by arrow F in Figure 16, to snap off the connections 86, freeing the expandable member from the holding means.

Figure 21 shows a view of one type of holding means 70 adapted for use with an insertion element 58 in the shape of a rivet. Such an insertion element and holding means are also described above with reference to Figures 6 and 14. The element 58 has an axial channel 40. The generally cylindrical holding means 70 has an inside diameter (**d**) greater than the outside diameter of the distal end 14 of expandable member 10, and great enough to accommodate the diameter of distal projection 38 of insertion element 34, as described above in Figure 5. The expandable member 10 includes frangible membrane 84. The expandable member 10 passes without resistance into a bone hole as described above generally, and the member is positioned within the hole so that in an externally smooth neck portion 31 projects above the bone surface to provide a stand-off between the radial projection 60 of the insertion element and the bone surface. An annular projection 95 on the neck 31 may retain the washer (not shown) of the rivet insertion element 58, preventing loss of the washer during insertion of the expandable member into the bone hole. The bore of

the washer is designed to receive the expandable member prior to emplacement of the bone fastener of the invention.

The outer diameter (b) of the insertion element 58 is about the same as or slightly smaller than the inner diameter of the neck portion 31 of the expandable member. Outer diameter (b) is larger than the inner diameter (a) of the axial channel 18 of the expandable member 10 so that, as the rivet shaft is compressed into the axial channel 18, it passes without resistance through the neck portion 31 but causes the outer, bone engaging surface 13 to expand outwardly against the wall of the bone hole. That is, as the rivet is urged frontward, the radial projection 38 at its proximal end 36 presses outward against the inner surface 19 of the axial channel.

Moreover, the outer diameter (c) of radial projection is sized to interfere with the axial releasing structure (e.g., frangible membrane 84) . When this occurs, the progress of the rivet within the expandable member 10 is momentarily stopped. Further frontward compression of the rivet 58 drives its radial projection 60 through the frangible membrane 84 and causes a failure of the frangible membrane portion, effecting separation of the fully installed rivet from the holding means 70. Then, the holding means 70 can be withdrawn from the site. Preferably, lower surface 66 of radial projection 60 is provided with an abrupt proximal edge to effect a shearing action. A circular undercut 96 on the frangible membrane further improves the precision of the separation. Thus, the resulting rivet is anchored firmly in place within the bone hole by intimate contact of the outer surface of the expandable member with the bone hole. Further, the material to be fastened by the rivet is confined about the supported neck portion of the expandable member between the bone surface and the washer of the rivet. As described above with regard to Figure 6, projections 67 on the rivet washer 62 serve to further engage the tissue with the fastener system.

The method of inserting an expandable member 10 in the shape of a rivet (as shown in Fig. 3) is substantially identical to the method described

previously for the insertion element rivet. Thus, the proximal end 12 of the expandable member 10 is contoured to pass easily through tissue. The distal, radial projection 23 on the expandable member is attached to holding means 70 by way of a frangible membrane 84, as described above. The membrane may be detached by the methods described previously, thereby freeing the fully expanded and firmly fixed rivet fastener from the holding means. The holding means is then withdrawn, leaving the expandable member rivet in place at the fixation site of the bone, compressing the attached tissue between the prominal end of the radial projection and the surface of the bone. An alternate configuration for use in the rivet described immediately above, includes an annular undercut 98 on an inner surface of the radial projection 23, this excavation being just proximal to the frangible membrane 84. The undercut is formed sufficiently deeply into the material of the radial projection 23 so that when the frangible membrane is cut or otherwise severed, an annular fragment is cut free of both the radial projection 23 and the expandable member (not shown), and any remaining connection between the radial projection and the expandable member being so thin has to provide little resistance to simply pulling the holding means away from the fixed fastener. All other reference numbers are as previously described.

E. Apparatus

A preferred emplacement apparatus of the invention retains the holding means and expandable member prior to emplacement. The emplacement apparatus includes means for pressing the insertion element into the expandable member and then separating the expandable member from the emplacement apparatus. The fastener assembly can include a disposable cartridge, the cartridge containing the expandable member, insertion element, holding means, and means for attaching the disposable cartridge to the apparatus.

Figure 23 is one embodiment of an emplacement apparatus of the invention. Its operation is best exemplified by reference also to Figures 18 and

19. The apparatus 99 includes a cartridge 100 which encloses holding means 70 attached by axially releasing membrane 84 to expandable member 10. The cartridge is preloaded with plunger 90 and insertion element 34. A releasing element 92 (not shown in Figure 23) is co-axially arranged around plunger 90 to activate the axial releasing structure (e.g., sever the membrane 84). The insertion element 34 is positioned with its proximal projection 36 in facing relationship to distal end 14 of the expandable member 10. Insertion element 34 is provided with a suture 46. The free ends of the suture pass through the axial channel 40, through channel 106 of the plunger 90, and are knotted against the proximal end 36 of the insertion element 34. The knot 44 is fully contained within the expandable member 10 prior to its emplacement in the bone hole, so that it cannot interfere with the insertion into the hole.

The cartridge 100 may additionally include a take-up spool 112, for storage of the free ends of suture 46. When the apparatus is loaded, suture 46 is arranged to pass from the knot in proximal end 36 of insertion element 34, through axial channel 40, through a hole in plunger axial channel 106, and over and around spool 112. As the apparatus is withdrawn, leaving the fastener with the suture 46 attached fixed in place in the bone hole, as described above with reference to Figures 18-19, the free ends of the suture 46 pay off from the take-up spool 112.

Cartridge 100 is removably attached to hand-held means for urging the plunger 90 frontward (i.e., towards the bone) with respect to the cartridge. In the configuration of Figure 23, the hand-held means 120 consists of two handle elements 122, 124 slidably engaged to provide a comfortable pistol grip 126 by which handle element 124 can be moved in a front-and-rear direction with respect to the handle element 122 by squeezing the pistol grip 126. The end 123 of the handle element 122 is adapted for removably mounting the distal end 101 of cartridge 100. The end 125 of handle element 124 includes a push rod 129 whose proximal end 127 abuts the distal end 91 of plunger 90 when the handle elements are assembled and the cartridge 100 is mounted onto end

123 of handle element 122. Alternatively, an axial bore 130 can be arranged to pass rearward through push rod 129 and handle element 124 for conducting the suture distally from the knot at the proximal end of the expandable element all the way to the outside.

With the apparatus so assembled, the surgeon grasps the apparatus by the pistol grip, and directs the expandable member to the desired depth into the predrilled hole in the bone. Then, while holding the apparatus in place, the surgeon squeezes the grip 126 sliding the handle 124 frontward with respect to the handle element 122, as indicated by the arrow 131. The push rod 129 presses against distal end 91 of plunger 90, urging the plunger in a non-impulse fashion towards the holding means 70, and thereby: (i) compressing element 34 into the axial channel 18 of expandable member 10; (ii) causing the expandable member 10 to expand within the bone hole 33; and (iii) causing releasing element 92 to sever the frangible membrane 84 between the expandable member 10 and the holding means 70, leaving the fastener fixed in the bone.

An alternate embodiment is shown in the exploded view of Figure 24. All reference numbers are identical to those in Figure 23, unless noted otherwise. The holding means 70 is connected at its distal end by a quick-connecting interlock 500 with the hand-held means 120 for urging a plunger 90 frontward with respect to the expandable member 10. The apparatus includes a lock mechanism 142 having a series of slots or teeth 143 for gripping the distal end 144 of holding means 70. A cap 146 and cap insert 148 are also provided to co-axially engage the lock 143. An actuator drive rod 150 is positioned within the hand held means and is co-axially arranged with spring 152. The drive rod, connected to handle 122, is forced against plunger 90, as described above. Preferably the snap-on interlock is configured as an insertible, spring-loaded connector, in which a distal portion of the holding means forms the "male" part of the connector and a portion of the hand-held means forms the "female" part. With reference to Figure 24, a flange 510 is

situated with a rear surface 512 situated a fixed distance distal to the frangible membrane 84 connecting the expandable member 10 to the holding means 70. Distal to the flange 510, is a groove 514 having a frontward-facing surface 516 generally perpendicular to the longitudinal axis of the holding means. The holding means tapers distally from the outer edge of the surface 516. The hand held means is provided with a generally cylindrical bore for receiving that portion of the holding means situated distal to the flange.

The hand-held means 120 is provided with one or more keepers (not shown) that are moved away from its longitudinal axis by the advancing taper 518. The keepers then spring into the groove 514 and lock against frontward-facing groove surface 516 when the distal portion of the holding means is correctly positioned within the receiving bore of the hand-held means. The rear-facing surface 512 of the flange 510 contacts a part of the hand-held means adjacent the holding means receiving bore to provide a stop establishing the correct rearward position of the holding means within the hand-held means.

The hand-held means 120 is provided with a plunger 90 that can be continuously urged proximally with respect to the holding means receiving bore along the holding means longitudinal axis. Continuously and without impulse, the insertion element is driven toward, and into, the axial channel of the expandable member. The plunger 90 includes a shoulder 520 at its proximal end. An edge of the shoulder provides a sharpened surface sufficient to activate the releasing structure by severing frangible membrane 84.

Preferably, the length of the plunger is fixed in relation to the fixed front-to-rear distance between the rear surface 512 and the frangible membrane connecting the expandable member to the holding means. A stop is provided to limit the extent frontward to which the plunger can be urged within the hand-held means, so that the disengagement of the expandable member from the holding means is complete at just the point where the plunger has been moved to its proximal limit. This ensures proper emplacement of the fastener in the bone hole, provided that the holding means is properly mounted in the handle

and the user urges the plunger frontward as far as it will go.

The foregoing will be further illustrated by the following Example.

Example

An expandable member is formed of natural high density polyethylene ("PE"), type PDC 9122, supplied by Dow Chemical Co. (Dow HD8354N) and dimensioned to slide easily into a 0.138 inch (3.5 mm) diameter bone hole. The outer surface of the member is molded to a 6-32 screw thread configuration to provide screw threads. A 6-32 screwthread configuration provides a 0.138 inch outermost diameter so that the member can be inserted into a 3.5 mm bone hole without resistance. The axial channel of the member is of a uniform 0.070 inch (1.8 mm) diameter, and its length is 0.422 inches (10.3 mm).

The insertible element is formed of DuPont Delrin II 500, molded to have the general shape shown in Figure 4 and an outermost diameter of 0.107 inch (2.7 mm). Delrin is much less deformable than the polyethylene of which the expandable member is made. The proximal leading edge of the insertion element permits the relatively incompressible element to be forced into the 0.070 inch expandable member axial channel and to expand the relatively soft expandable member. When the insertion element has been fully inserted within the expandable member, the device has an outermost diameter approximately 0.160 inch (4.1 mm), providing for substantial deformation of the outer surfaces of the expandable member into the irregular wall of the bone hole, and thereby forming a firm fastener for the expandable member and insertion element. The element has an axial channel of diameter 0.046 inches (1.1 mm), which accepts a pair of sutures for later use in attaching soft tissue to the bone surface. Before insertion of the element, the sutures are passed through the axial channel of the insertion element and their proximal ends are knotted so that they stop against the proximal end of the insertion element.

The outside configuration of the membe. is a 6-32 thread which provides

a series of ridges which assist in permitting deformation of the expandable member in the bone hole and conformation of the expandable member outer surface as it is pressed into the 0.138 inch (3.5 mm) diameter bone hole. In this prototype, the threads are not used for turning the expandable member into the bore, but rather to facilitate deformation of the outer portion of the member when the member is expanded within the bone hole. When the insertion element is inserted into the axial channel of the expandable member, the threads are deformed by irregularities in the cancellous bone hole wall, locking the fastener, and the element compressed within it, into place.

The expandable member is formed with frangible, integral connection to a cylindrical holding means as described above, enclosed within a cartridge, and provided with the apparatus as described above, configured and dimensioned as follows:

The holding means, for example as shown in Figure 24, is formed as a cylinder having inside diameter of 0.145 inches (3.7 mm), outside diameter 0.230 inches (5.8 mm), and a total length of 6.0 inches (152 mm). The frangible membrane between the holding means and the expandable member is formed as an annulus having a thickness of 0.012 inches (.30 mm).

The plunger and releasing means are constructed by turning a stainless steel rod to provide a punch-and-die configuration (generally as in Figure 24) having an outer diameter of 0.145 inches (3.7 mm). The severing means is formed by machining the end of the rod to form a sharpened step, located approximately 0.060 inches (1.5 mm) distal to the blunt proximal tip of the plunger.

As the plunger is pressed frontward, it presses the insertion element before it into the axial channel of the expandable member, expanding it and deforming it against the bone hole wall. When the element approaches the point where it has been pressed fully into the member, the sharpened step reaches the 0.012 (0.30 mm) inch thick connecting annulus and passes through it, shearing it and separating the expandable member from the holding means.

Then the cartridge is withdrawn together with the plunger and the holding means, leaving the fastener fixed within the predrilled bone hole.

A 3.5 mm (0.138 inch) diameter hole is made in the bone to a depth of about 14 mm using a drill with a stop to limit the hole depth. The prototype device is emplaced as described above, in femur bone recovered from a pig cadaver, and then is tested as follows.

The hole is drilled into the pig femur approximately normal to the bone surface to a depth about 14.25 mm using a step drill. Then a fastener is loaded with a pair of #2 non-sterile braided polyester sutures coupled to a hand-held means, positioned, and fixed in the bone hole as described above. A knot is tied in the sutures at some distance from the fastener and looped over an Ametek Accuforce Cadet digital force gauge, 0-50 lbs. range (Mansfield & Green). The slack in the sutures is taken up by drawing the force gauge by hand away from the fastener in a direction perpendicular to the bone surface. The holding force is then tested by sharply pulling the force gauge away from the bone by hand in a direction perpendicular to the bone surface. In such preliminary tests, the fastener held and the suture broke. These results demonstrate a holding capacity equivalent to those shown in similar tests using known devices now on the market.

The fastener according to the invention provides a platform to secure the suture because it is locked into dense bone, and because the conformity of the expandable member surface with irregularities in the bone provides efficient fixation. Moreover, there are no sharp edges in the fastener that can abrade the suture.

The bone fastener according to the invention can be used for fastening bone to any of a variety of objects, including tissues such as ligaments or tendons and prostheses such as bone plates. The fastener and emplacement apparatus can be used in any of a wide variety of orthopedic surgical procedures and settings. The fastener can provide superior holding capacity and relatively small size, and can be installed according to the invention without

impulse, impact or hammering and without imposing any substantial net force toward or away from the bone surface, and so the invention provides for fastening in surgical settings in which bone anchors have not been used, or have been used with limited success.

The fastener according to the invention is of a readily drillable material, and the installed fastener is situated near the bone surface. Thus, removal of the device from the bone in a later surgical procedure is straightforward. If removal of a fastener is indicated, the surgeon can simply use a retrieval device, consisting of for example, a drill bit, preferably of a somewhat smaller diameter than the original bone hole. The drill bit can be used to excavate the insertion element and then the anchor and any debris can be simply withdrawn from the hole.

The Suture Grasper

Referring now to the drawings, and particularly to Figs. 1' and 2', a suture grasping tool 5' is shown which comprises a rigid, hollow shaft 10', a rod 12', a first elongated wire-like element 15', a second elongate wire-like element 20', and an actuation device 25'.

More particularly, the rigid, hollow shaft 10' includes a proximal end 30', a proximal portion 35' adjacent to proximal end 30', a pointed distal end 40', a distal portion 45' adjacent to distal end 40', and a central lumen 50' extending between proximal end 30' and distal end 40'. In a preferred embodiment of the invention, the inner and outer diameters of proximal portion 35' of shaft 10' are larger than the respective inner and outer diameters of distal portion 45' of shaft 10'. In accordance with one preferred embodiment of the invention, distal portion 45' of shaft 10' is curved. Of course, it should also be appreciated that distal portion 45' of shaft 10' could be formed straight if preferred.

Rod 12' is a solid element having a proximal end 55' and a distal end 60'. Rod 12' is telescopically located in the proximal portion 35' of shaft 10'.

More specifically, rod 12' has a longitudinal length slightly greater than the longitudinal length of proximal portion 35' of shaft 10'. Accordingly, rod 12' may be moved between (i) a proximalmost position wherein distal end 60' of rod 12' is spaced proximally from the point where the proximal and distal portions of shaft 10' meet (see Fig. 1'); and (ii) a distalmost position wherein the distal end 60' of rod 12' is substantially aligned with the point where the proximal and distal portions of shaft 10' meet (see Fig. 2').

First and second wire-like elements 15' and 20' each have a proximal end 65', 70' and a distal end 75', 80', respectively (see Fig. 4'). Proximal ends 65' and 70' of wire-like elements 15' and 20' are attached to distal end 60' of rod 12', whereby wire-like elements 15' and 20' move in conjunction with rod 12'. In addition, at least the distal ends 75' and 80' of the respective wire-like elements 15' and 20' normally bend or flare away from each other. Furthermore, the first wire-like element 15' is bent radially inwardly immediately adjacent to its distal end 75' so as to form a substantially hook-shaped configuration, generally indicated at 85'.

The longitudinal lengths of first and second wire-like elements 15', 20' are selected such that when rod 12' is in its proximalmost position (Fig. 1'), distal ends 75' and 80' of first and second wire-like elements 15' and 20' will be located within distal portion 45' of shaft 10'. In this position, distal ends 75' and 80' of first and second wire-like elements 15' and 20' will be disposed in closely spaced relation to one another (see Fig. 7'). When rod 12' is in its distalmost position (Fig. 2'), however, distal ends 75' and 80' of first and second wire-like elements 15' and 20' will project outwardly from distal end 40' of shaft 10'. In this position, distal ends 75' and 80' of first and second wire-like elements 15' and 20' flare outwardly away from one another (Fig. 4').

Actuation device 25' is attached to proximal end 30' of shaft 10' and to proximal end 55' of rod 12'. In this embodiment, actuation device 25' includes a housing 90' attached to proximal end 30' of shaft 10'. Housing 90' defines

a cylindrical cavity 95' which is aligned with, and opens into, lumen 50' of shaft 10'. A trigger 100' is pivotally attached to housing 90', and extends into cavity 95'. A piston-like element 105' is securely attached to the proximal end 55' of rod 12', and is located in reciprocally sliding relation within the housing's cavity 95'. A spring 110' biases piston-like element 105' proximally so that rod 12' will normally assume its aforementioned proximalmost position (Fig. 1'). Piston-like element 105' may be moved distally against the force of spring 110' by trigger 100' so that rod 12' will assume it aforementioned distalmost position (Fig. 2').

It will, therefore, be understood that rod 12' normally resides in its proximalmost position (Fig. 1') and distal ends 75' and 80' of the two wire-like elements 15' and 20 normally reside within distal portion 45' of shaft 10'. It is to be appreciated that when distal ends 75' and 80' of the two wire-like elements 15' and 20' reside within distal portion 45' of shaft 10', the pointed distal end 40' of shaft 10' may be forced through tissue without interference from distal ends 75' and 80' of wire-like elements 15' and 20' or from a length of suture which may be grasped thereby.

Device 5' may be used to grasp and manipulate a piece of suture 115' at a surgical site. Among other things, it may also be used to grasp a piece of suture 115' on either the left side 118' or the right side 119' of a tissue 120', and to pass that suture through the one or more layers making up tissue 120'. The passage of suture 115' through tissue 120' may be accomplished either by pulling the suture through, or by pushing the suture through, tissue 120'.

More particularly, in those cases where it is desired to pull suture 115' through tissue 120' from tissue side 118' to tissue side 119', the steps of the method are illustratively shown in Figs. 3' through 10'. Starting from the position where suture 115' is located on tissue side 118' and distal end 40' of shaft 10' is located on tissue side 119' as shown in Fig. 3', the pointed distal end 40' of shaft 10' is first forced through tissue 120'. Then shaft 10' is manipulated so as to bring its distal end 40' sul .tantially adjacent to the portion

of suture 115' which is to be carried back through tissue 120'. Next, trigger 100' is activated so as to move rod 12' toward its distalmost position. This causes the distal ends 75', 80' of wire-like elements 15', 20' to extend out of distal end 40' of shaft 10' so that the wire-like elements flare away from each other. Device 5' is then manipulated further as needed so as to position suture 115' in the gap 121' formed between distal ends 75', 80' of first and second wire-like elements 15', 20' (see Fig. 4').

Trigger 100' is then released so as to allow rod 12' to move toward its proximalmost position under the influence of the spring 110'. As this occurs, distal ends 75', 80' of the wire-like elements 15', 20' retreat back into distal portion 45' of shaft 10', and the wire-like elements 15', 20' move back toward one another as they re-enter distal portion 45' of shaft 10'. During this retraction of the wire-like elements, hook 85' adjacent distal end 75' of first wire-like element 15' grapples the portion of suture 115' which is located within the closing gap 121' (see Fig. 5') and carries it toward distal end 40' of shaft 10'.

As hook 85' enters distal end 40' of shaft 10', a portion of suture 115' also is drawn into the distal end of the shaft. Suture 115' is held in this position by the spring-biased hook 85' acting in co-operation with the distal end of shaft 10' (see Figs. 6' and 7').

Hook 85', shaft 10' and suture 115' may be sized so that the suture is tightly bound to the shaft. Alternatively, the hook, the shaft and the suture may be sized so that suture is free to slide transversely relative to hook 85' inside the distal portion of the shaft.

Distal portion 45' of shaft 10' is then withdrawn from tissue 120', carrying the grappled suture 115' with it (see Fig. 8'). Thereafter, suture 115' is released from device 5' by squeezing trigger 100' again. This causes wire-like elements 15', 20' to project outwardly from distal end 40' of shaft 10' in flaring relation to one another (see Fig. 9'). Suture 115' then is released from tool 5' by manipulating the tool and/or the suture so that the suture no longer

resides in gap 121' between distal ends 75', 80' of wire-like elements 15', 20' (see Fig. 10').

The procedure for pushing suture 115' through tissue 120' from tissue side 119' to tissue side 118' is somewhat similar in nature and is generally illustrated in Figs. 11' through 16'. Specifically, distal end 40' of shaft 10' is first positioned adjacent to suture 115' on tissue side 119' (see Fig. 11'). Trigger 100' is then squeezed so as to project the wire-like elements 15', 20' outwardly from distal end 40' of shaft 10', in flaring relation to one another. Thereafter, device 5' is manipulated so that suture 115' resides in gap 121' between the distal ends of wire-like elements 15', 20' (see Fig. 12').

Trigger 100' is then released so as to allow the distal ends of wire-like elements 15', 20' to retract back into the distal portion of shaft 10' under the influence of spring 110'. The distal ends of the two wire-like elements 15', 20' to move back toward one another as they re-enter distal portion 45' of shaft 10', closing down gap 121'. As this occurs, hook 85' grapples suture 115' and draws the grappled portion against distal portion 45' of shaft 10'. The engagement of suture 115' with distal end 40' of shaft 10' is such that the distalmost point 122' of distal end 40' is located distally of grasped suture 115' and wire-like elements 15', 20' (see Fig. 13').

In this configuration, distal end 40' of shaft 10' is forced through tissue 120', carrying grappled suture 115' with it (see Fig. 14'). Trigger 100' is then squeezed once again so as to project wire-like elements 15', 20' out of the distal end of shaft 10', in flaring relation to one another (see Fig. 15'). Then tool 5' and/or suture 115' are manipulated so that suture 115' no longer sits in gap 121'. This frees the suture from the tool. Then trigger 100' is released so as to retract wire-like elements 15' and 20' back into shaft 10'. Shaft 10' is then withdrawn from tissue 120', leaving suture 115' extending through tissue 120' (see Fig. 16').

A suturing procedure requiring multiple passes of suture 115' through one or more layers of tissue also can be conveniently accomplished with device

5'. For example, device 5' might be used to first pull a length of suture 115' through tissue 120', and thereafter to push that same suture 115' back through tissue 120' at a location adjacent to the first pass of the suture through the tissue. Alternatively, suture 115' could first be pushed through tissue 120', and thereafter pulled back through the tissue at a location adjacent to the first pass of the suture through the tissue.

Looking next at Figs. 17'-32', a representative suturing operation will be described for purposes of illustration.

Fig. 17' shows tissue 120', a length of suture 115' adjacent side 119' of tissue 120', and distal portion 45' of a device 5' formed in accordance with the present invention. Tissue 120' is shown as including layers 120'a and 120'b in abutting relationship to one another so as to represent the capability of device 5' to secure together multiple layers of tissue.

Figs. 18'-22' respectively show (i) engagement of wire-like elements 15', 20' with suture 115'; (ii) grasping of suture 115' to distal end 40' of device 5'; (iii) pushing the distal portion of shaft 10' through tissue 120', carrying suture 115' therewith; (iv) release of suture 115' from distal end 40' of shaft 10'; and (v) disengagement of wire-like elements 15', 20' from suture 115' and withdrawal of distal portion 45' from tissue 120', leaving suture 115' extending therethrough. The details of this procedure are the same as those just described with respect to pushing a length of suture through tissue.

Figs. 23'-28' illustrate the use of the same procedure to pass the free end of suture 115' left adjacent to side 119' of tissue 120' back through tissue 120' at a location spaced from the first pass of the suture through tissue 120'. Accordingly, it will be seen that in Fig. 28' both free ends of suture 115' have been pushed from tissue side 119' through tissue 120' to tissue side 118'.

Finally, Figs. 29'-32' illustrate the use of the pulling technique described above to draw one of the free ends of suture 115' from tissue side 118' back through tissue 120' to tissue side 119'. This third pass of suture through tissue 120' takes place at a location spaced from the first two passes of suture 115'

through tissue 120'.

In some situations it may be desirable to be able to adjust the orientation of the distal portion of the shaft without changing the orientation of the tool's handle. Another preferred embodiment of the invention addresses this situation. In this embodiment, the device 205' (best seen in Figs. 33' and 34') comprises a suture grasper assembly 300' (best seen in Fig. 35') and an actuation means 305' (best seen in Figs. 33' and 34'). More particularly, and as best seen in Fig. 36', suture grasper assembly 300' includes a wire subassembly 400', a shaft subassembly 500' and a housing subassembly 600'.

Wire subassembly 400' (best seen in Figs. 37' and 38') includes at least one wire 402', a rigid tube 404' and a flexible sheath 406'. Each of the wires 402' has a distal end 408', a proximal end 410' and a principle longitudinal axis 412'. Further, each wire 402' defines a bend 403' at an angle of about 30° relative to its principle longitudinal axis 412'. Bend 403' is located close to the wire's distal end 408'. Each wire 402' has an equal length as measured between its proximal end 410' and its bend 403'. In the case where only a single wire 402' is used, wire 402' is bent substantially adjacent to its distal end 408' so as to form a hook-like configuration 414'. In the case where multiple wires 402' are used, at least one of the wires 402' is bent so as to form a hook-like configuration 414' as just described.

Tube 404' is typically made of stainless steel. It includes a distal end 416', a substantially straight distal portion 418' adjacent to distal end 416', and a substantially straight proximal portion 420' which extends at a substantially right angle to distal portion 418'. Tube 404' terminates at a proximal end 422'. Each of the wires 402' is secured to the proximal end 422' of tube 404'. Each of the wires 402' also extends through both the distal and proximal portions 418', 420' of tube 404' so that bend 403' is spaced distally from distal end 416' of tube 404'.

Flexible sheath 406' is made of a heat shrink material, and has an axial length greater than the separation of bends 403' of wires 402' and distal end

416' of tube 404'. Flexible sheath 406' tightly covers the wires 402' and overlaps distal end 416' of tube 404'. Accordingly, sheath 406' secures wires 402' together such that the portions of the wires located distally of bends 403' flare outwardly relative to one another, and the portions of the wires located immediately proximally of bends 403' can flex relative to their respective longitudinal axes 412'.

Shaft subassembly 500' (best seen in Fig. 39') includes a hollow shaft 502', a normally curved tip 504' and a drive rod 506'. Shaft 502' has a distal end 508' and a proximal end 510', and defines an inner lumen 512' which has a substantially constant diameter along its length. Shaft 502' also includes a longitudinal slot 514' which extends distally from proximal end 510'. Further, a counterbore 516' extends distally from proximal end 510' of shaft 502'. One end 518' of drive rod 506' is received in counterbore 516', and is secured therein by any convenient and reliable means, e.g. by welding. A pair of circumferential grooves 520', 522' are provided in drive rod 506' adjacent to its proximal end 524'.

Wire subassembly 400' is located in lumen 512' of shaft 502' such that the proximal portion 420' of wire subassembly 400' extends through longitudinal slot 514', and is reciprocally movable within slot 514'. The length of wire subassembly 400' (as measured between proximal portion 420' and bends 403') is selected such that when proximal portion 420' of wire subassembly 400' engages the distal end of slot 514', the flared portions of wires 402' will extend beyond distal end 508' of shaft 502'. Further, the longitudinal length of slot 514' is selected such that when proximal portion 420' of wire subassembly 400' engages distal end 518' of drive rod 506', the flared portions of wires 402' will reside within lumen 512' of shaft 502'.

Housing subassembly 600' (see Fig. 36') includes a bearing 602', an outer housing 604', a compression spring 606', an inner housing 608', a cylindrical gear 610' and an end cap 612'.

Bearing 602' (best seen in Figs. 40'-4. ') is a hollow cylindrical member

having a proximal end 614', a distal end 616', and an outer surface 618'. The hollow center of bearing 602' is adapted to receive shaft 502' therethrough The outer surface 618' is relieved adjacent to proximal end 614' and adjacent to distal end 616' so as to define a pair of oppositely facing annular shoulders 620', 622' separated by a middle portion 624'. Further, a longitudinal slot 626' extends from proximal end 614' to a closed end 628' located in middle portion 624'. Slot 626' has a width slightly greater than the diameter of proximal portion 420' of wire subassembly 400'. Accordingly, bearing 602' may be telescoped over distal end 508' of shaft 502' so that the proximal portion 420' of wire subassembly 400' (which projects through slot 514' in shaft 502') engages closed end 628' of bearing slot 626'.

Outer housing 604' (best seen in Figs. 43' to 46') includes a distal end wall 630' having a central opening 632' therethrough, an open proximal end 634', and a cylindrical side wall 636', which elements together define a substantially cylindrical, open-ended cavity 638'. A longitudinal slot 640' extends distally from proximal end 634' for about one-half of the axial length of outer housing 604'. The width of slot 640' is approximately the same as would be achieved by the removal of about 90° of side wall 636'. In addition, a threaded counterbore 642' is formed around the distalmost portion of opening 632'.

Compression spring 606' (best seen in Fig. 36') is located within distal portion 644' of cavity 638' such that one end 646' of the spring bears against distal end wall 630' of outer housing 604' about opening 632'. Shaft subassembly 500' (carrying bearing 602' as described above) is inserted distal end first through housing open end 634', through spring 606', and through housing opening 632'. As a result of this construction, the other end 648' of spring 606' bears against shoulder 622' of bearing 602'.

Inner housing 608' (best seen in Figs. 47' to 50') is reciprocally located within cavity 638' of outer housing 604'. Inner housing 608' includes a substantially circular distal end wall 650' having a centered opening 652'

therethrough, a side wall 654' extending proximally from distal end wall 650', and a proximal end 665'. A pair of opposing projections 656', 658' extend circumferentially into gap 660' from side edges 662', 664' of sidewall 654'. If desired, the alignment of gap 660' of inner housing 608' with slot 640' of outer housing 604' may be assured by the provision of a groove 666' in distal end wall 650'. Groove 666' will receive an elongated, longitudinal projection 667' formed on outer housing 404'. Furthermore, the distal end wall 650' receives the relieved proximal portion of bearing 602' such that the distally facing surface of distal end wall 650' bears against shoulder 620' of bearing 602', thereby trapping proximal portion 420' of wire subassembly 400' in bearing slot 626'.

A cylindrical gear 610' (best seen in Figs. 51' and 52') resides on drive rod 506' within inner housing 608'. Gear 610' includes an axial opening 668' which is adapted to receive drive rod 506'. Gear 610' is made out of a substantially resilient material so that it elastically engages the outer surface of the drive rod. Outer surface 669' of gear 610' carries a plurality of generally helical flights 670'. Accordingly, while gear 610' may slide along drive rod 506' somewhat during the projection and/or retraction of wire subassembly 500', its engagement with drive rod 506' is such that applied forces tending to rotate gear 610' also tend to rotate shaft 502'.

End cap 612' (best seen in Figs. 53' and 54') is a generally semi-cylindrical member adapted to lock the elements of housing subassembly 600' together. To accomplish this, an opening 672' is provided midway along flat edge 673' of the cap's semi-cylindrical structure. The opening 672' is adapted to engage the drive rod's circumferential groove 520' adjacent to its distal end 524'. Further, the periphery of cap 612' is adapted to engage sidewall 636' of outer housing 604' in a snap-fit or other secure manner.

Since there may be some play among the components of suturing device 205', and since such play can prove inconvenient when penetrating hard tissue with the sharp distal tip of the device, a lock nut 674' (best seen in Figs. 55'

to 57') also may be provided. Lock nut 674' can lock shaft subassembly 500' against rotation relative to actuation means 305'. Lock nut 674' includes a cylindrical shaft 676' having a distal end 678', a proximal end 680', an outer surface 682' carrying threads 684', and an annular flange 686' extending radially outwardly from cylindrical shaft 676' adjacent to distal end 678'. Cylindrical shaft 676' also includes a pair of opposing longitudinal slots 688', 690' extending distally from proximal end 680' to closed ends 692'. Further, annular flange 686' defines an outer edge 694' which may be knurled to facilitate rotation of lock nut 674'.

Lock nut 674' is telescoped proximal end first onto the distal portion of shaft subassembly 500' and moved into engagement with threaded counterbore 642' in outer housing 604'. The outer diameter of shaft 676' and the diameter of counterbore 642' are selected such that as the lock nut's shaft 676' is progressively screwed into counterbore 642', the portions of the lock nut located between slots 688' and 690' will be squeezed inwardly against shaft 502'. Accordingly, shaft 502' may rotate about its longitudinal axis when the lock nut engages only the distalmost portion of counterbore 642', but is prevented from rotating relative to outer housing 604' when the lock nut's shaft 676' is fully engaged within counterbore 642'.

It will, therefore, be seen that the suture grasper assembly 300' normally retains the wire(s) 402' in their retracted position within shaft subassembly 500'. Specifically, compression spring 606' normally urges inner housing 608' against end cap 612'. Since the proximal portion 420' of wire subassembly 400' engages bearing 602' which is rotatably located in the central opening 652' in distal end wall 650' of inner housing 608', proximal portion 420' of wire subassembly 400' is urged against end 518' of drive rod 506' when inner housing 608' is in its proximalmost position within outer housing 604'.

Actuation means 305' comprises a handle 702', a third housing 704' defining a substantially cylindrical cavity 706', and a pair of triggers 708' and 710' pivotally mounted to third housing 704'. Third housing 704' is adapted

to receive outer housing 604' such that (i) an end 712' of first trigger 708' engages the circumferential projections 656', 658' of inner housing 608', and (ii) a curved end 714' of second trigger 710' (carrying spaced teeth 716') engages gear 610'. Further details of the construction of actuation means 305' are set forth in copending U.S. patent application Serial No. 07/959,121, which is presently assigned to Innovasive Devices, Inc. of Hopkington, Massachusetts, which is also the assignee of this application. U.S. patent application Serial No. 07/959,121 is specifically incorporated herein by reference.

In view of the foregoing construction, a surgeon may grasp handle 702' and rotate first trigger 708' toward handle 702' with one hand. As first trigger 708' is rotated in this fashion, inner housing 608' is urged along shaft subassembly 500' toward distal end wall 630' of outer housing 604'. This movement takes place against the force of spring 606'. Movement of inner housing 608' relative to outer housing 604' causes proximal portion 420' of wire subassembly 400' to be urged distally along slot 514'. This movement of proximal portion 420' of wire subassembly 400' urges the distal ends of wire-like elements 402' to project out the distal end 508' of shaft subassembly 500', for use in grasping a suture as described above.

When the surgeon wishes to rotate shaft subassembly 500' relative to actuation means 305', the surgeon pulls second trigger 710' toward handle 702'. Such manipulation of second trigger 710' causes gear 610' to rotate within inner housing 608'. Since gear 610' is mounted in substantially tight elastic contact around the distal portion of drive rod 506', the rotation of gear 610' causes axial rotation of shaft subassembly 500' and wire subassembly 400' as a unit.

Accordingly, the surgeon may, with one hand, (i) rotate a curved tip of the shaft subassembly about the longitudinal axis of the tool so that it faces in any desired radial direction, and/or (ii) move the wire subassembly from its retracted position toward its fully extended position. Further, since bearing 602' (holding proximal portion 420' of wire subassembly 400') is axially

rotatable relative to opening 652' in distal end wall 650' of inner housing 608', bearing 602' will rotate with the shaft subassembly 500', thereby avoiding undesirable twisting of the subassembly 400'.

The Suture Throw Rundown Instrument

Referring now to Fig. 1'', there is shown a surgical instrument which, in its preferred form, is a scissors designed for laparoscopic procedures. The instrument comprises a handle assembly 2'', a drive assembly 4'', a tool head 6'' in the form of a scissors head, and an electrical terminal pin 7''. The handle assembly may take various forms. In this preferred embodiment of the invention, the handle assembly comprises a fixed or stationary handle 8'', a movable handle member in the form of a trigger 10'' for operating the scissors head, and a rotation trigger member 12'' which cooperates with the drive means carried by the handle assembly to effect controlled rotation of the scissors head relative to the handle assembly.

Looking now at Figs. 2''-4'', the fixed handle 8'' comprises complementary left-hand and right-hand handpieces 16''L and 16''R that preferably are made of a plastic material such as a polysulfone or polycarbonate. These handpieces are complementary in the sense that they are mating halves of member 8'' and, except as otherwise stated hereinafter, handpieces 16''L and 16''R are identical mirror images of one another. Handpieces 16''L and 16''R have like circularly curved axially-extending elongate cavities 20''L and 20''R respectively on their mutually confronting sides. Additionally, handpieces 16''L and 16''R have axially-extending flat-sided grooves 22''L and 22''R that intersect cavities 20''L and 20''R respectively at the twelve o'clock position (Fig. 4''). Grooves 22''L and 22''R cooperate to define a keyway for an insulator housing 42'' (Figs. 5''-7'') described hereinafter that forms part of the drive assembly 4''. Handpieces 16''L and 16''R also have semi-circular cavities 24''L and 24''R that communicate with reduced-diameter semi-circular cavities 26''L and 26''R

respectively. Intersecting the cavities 24''L and 24''R are additional semi-circular cavities 28''L and 28''R which also intersect the cavities 20''L and 20''R respectively at right angles. Cavities 20''L, 20''R, 24''L, 24''R, 26''L, 26''R, 28''L and 28''R are semi-circular in the sense that they have a semi-cylindrical cross-section. The left handpiece 16''L is provided with three projections or pins 32''A, 34''A and 36''A of circular cross-section that are sized to make a close fit in like-spaced cavities or depressions 32''B, 34''B and 36''B in the right handpiece 16''R. Although provided for other purposes hereinafter described, pins 32''A, 34''A and 36''A serve incidentally as assembly registration pins for handpieces 16''L and 16''R.

Preferably, but not necessarily, one handpiece (16''L) has two or more locating pins 37''A that are sized and located so as to mate closely with shallow depressions or cavities 37''B in the other handpiece (16''R), so as to facilitate and assure proper registration of the two handpieces when they are engaged with one another in forming handle 8''. Handpieces 16''L and 16''R are secured together, preferably by a suitable cement such as an epoxy resin or by ultrasonic welding.

For reasons of convenience of use by the surgeon, it is preferred, but not essential, that the rear surface of the left and right handpieces have a knurled configuration as shown at 38''L and 38''R respectively so as to facilitate gripping of the handle unit. Additionally, it is preferred, but not essential, that the handpieces be provided with complementary finger holes 40''L and 40''R for receiving the thumb of the surgeon.

Drive assembly 4'' comprises an insulator housing 42'' and a tube housing 106'' (see Fig. 10'' and Figs. 5''-7'' and 18''-21''), plus components (other than tool head 6'') that are attached to housings 42'' and 106''.

Cavities 20''L and 20''R in the two handpieces cooperate to form a cylindrical chamber for receiving insulator housing 42''. The latter, which preferably is made of the same material as handpieces 16'', comprises a cylindrically shaped elongate section 44'' having a peripheral flange 46'' at its

forward or distal end so as to provide a shoulder 48'' that engages the forward end surfaces 50''L and 50''R of the left and right handpieces. Tubular section 44'' is formed with an external longitudinally-extending rectangular rib 52'' at the twelve o'clock position (as viewed in Fig. 7'') that is sized to make a close sliding fit in the keyway formed by grooves 22''L and 22''R of the left and right handpieces 16''L and 16''R respectively. In addition, tubular section 44'' has an axially-extending slot 56'' (Fig. 7'') formed symmetrically about the six o'clock position (as viewed in Fig. 7'') that serves as an access hole for portions of trigger members 10'' and 12'' and a slide hole for a portion of tube housing 106''. As viewed in Fig. 7'', slot 56'' terminates in side edge surfaces 84''A and 84''B. The circumference of section 44'' in the portion having slot 56'', i.e., the circumference measured between the outer edges of side edge surfaces 84''A and 84''B, measures about 260°, so that slot 56'' extends through an angle of about 100° (50° on either side of the six o'clock position). As viewed in Figs. 5''-7'', slot 56'' starts at the proximal (rear) end of section 44'' and ends close to the midpoint of housing 42'', leaving an arcuate end surface or shoulder 57'' (Fig. 6'').

Insulator housing 42'' has a center bore 60'' which is of constant diameter throughout its length, except that (1'') at its distal (front) end it is tapered as shown at 62'' and then communicates in turn with a smaller diameter hole 64'' and a bore 66'' that has a slightly larger diameter than hole 64'' so as to form an annular shoulder 65'', and (2'') it is formed with an internal rectangular axially-extending rib 78'' at the six o'clock position (as seen in Fig. 7''). Preferably the proximal (rear) end of rib 78'' is bevelled as shown at 79''. Affixed to the proximal (rear) end of the insulator housing 42'' is an end cap 80'' (Figs. 8'' and 9'') that preferably is made of the same material as handpieces 16''. End cap 80'' is generally circular in cross-section except that its circumference is less than a full 360°, so as to provide flat bottom surfaces 82''A and 82''B. Preferably its circumference, measured between the outer edges of surfaces 82''A and 82''B (as viewed in Fig. 8'')

measures about 240°. Consequently when cap 80'' is applied to housing 42'' so that its surfaces 82''A and 82''B extend parallel to bottom edge surfaces 84''A and 84''B, a portion of the rear end surface 58'' of housing 42'' in the region of the six o'clock position is not covered by cap 80'', so as to allow clearance between the cap and trigger 10'' when it is desired to pull the drive assembly out of the handle assembly.

Cap 80'' is provided with a radially-extending through slot 88'' that terminates at the center of the cap with a circularly curved hole 90'' that is concentric with the center axis of the cap. Also cap 80'' comprises a reduced diameter body section 92'' and a peripheral flange 94''. Body section 92'' is sized to make a close fit in the proximal end of the insulator housing, with flange 94'' having the same o.d. as tubular section 44''. The cap is ultrasonically welded or cemented, e.g., by an epoxy resin, to the proximal end surface 58'' of housing 42'', with the circularly curved hole 90'' being concentric with the hole 64'' of housing 42''.

As shown in Fig. 10'', insulator housing 42'' is disposed in the cylindrical chamber formed by the mating cavities 20''L and 20''R of handpieces 16'', with shoulder 48'' engaging the forward end surfaces 50''L and 50''R of those handpieces and rib 50'' being disposed in the keyway formed by grooves 22''L and 22''R. The interlocking of rib 52'' with the keyway formed by grooves 22''L and 22''R serves to dictate orientation of housing 42'' relative to the handle assembly. Housing 42'' is releasably secured in handle assembly 2'' by a locking action between a terminal pin 7'' and rod 100'' as hereinafter described.

Referring now to Figs. 10''-14'' and 18''-27'', drive assembly 4'' comprises, in addition to insulator housing 42'', the following elements: a support rod 100'' for tool head 6'', an outer operating tube or sleeve 102'', an outer sheath in the form of a tube 104'', and a tube housing 106''. The outer sheath 104'' is cylindrical and its proximal (rear) end extends into axial bore 66'' in engagement with shoulder 65'' and is fixed to the insulator housing by

a press fit or in some other suitable way, e.g., by an epoxy cement, as permitted by the materials being secured together. In this preferred embodiment, sheath 104'' is made of a suitable electrically insulating material, e.g., a fluorinated hydrocarbon such as Teflon, while tube 102'' may be made of an electrically-conductive metal or a conductive plastic. Tube 102'' has an outer diameter sized so that it makes a close sliding fit within outer sheath 104'' and also in the reduced diameter hole 64''.

Referring now to Figs. 18''-21'', tube housing 106'' preferably is made of a lubricious plastic material, e.g., molded DELRIN. Housing 106'' is a hollow member formed with a rectangular aperture 110'' that is centered about the six o'clock position and extends through about 100° of its circumference. Aperture 110'' is located just short of the proximal or rear end of the tube housing, so as to form a depending lug section 112'' which serves as part of the pivotal connection for the trigger member 10''. Housing 106'' also is provided with an axially-extending slot 114'' that intersects aperture 110'' and splits the lug section 112'' into two like parts 112''A and 112''B (Fig. 20''). Additionally, housing 106'' has an external axially-extending shallow groove 116'' located at approximately the six o'clock position. Groove 116'' is aligned with and has substantially the same width as slot 114''. Groove 116'' slidably mates with the elongate rib 78'' on the inner surface of insulator housing 42''. The sliding interengagement of groove 116'' with rib 78'' prevents the tube housing from rotating relative to insulator housing 42'' and also aligns aperture 110'' with slot 56''.

Referring now to Fig. 19'', the axial bore of tube housing 106'' is characterized by a first relatively large diameter section 122'', a tapered section 124'', a relatively small intermediate section 126'' and an intermediate diameter size section 128''. Axial bore section 126'' is sized to make a close sliding fit with support 100''. The intermediate size bore section 128'' is sized so as to tightly accommodate the proximal (rear) end of tube 102''. The latter is fixed to tube housing 106'' by a press fit or by other suitable means, e.g., by a

cement or by soldering, brazing or welding as is deemed practical according to the materials being joined.

Referring now to Figs. 11'' and 12'', for the majority of its length, rod 100'' has a constant relatively large size diameter as shown at 134''. The proximal end of rod 100'' is provided with a rounded head section 136'' which is sized to make a close fit in the rounded rear end of the chamber formed by the mating cavities 28''L and 28''R. Intermediate sections 134'' and 136'' the rod has two reduced diameter sections 138'' and 140'' that are separated by an intermediate flange section 142'' which preferably has a diameter close to that of rod section 134''. An annular shoulder 141'' is formed by the rod at its section 138''. The opposite or distal end of rod 100'' is formed so as to accommodate the tool head 6''. Further details of the construction of the forward or distal end of support rod 100'' are presented hereinafter.

The proximal (rear) end of rod 100'' slidably extends through the bore section 126'' of tube housing 106'' and its intermediate or reduced diameter section 138'' is accommodated by and makes a close fit in the circularly curved center hole 90'' of cap 80''. The radius of the hole 90'' of cap 80'' is smaller than the radius of the flange section 142'' of the drive rod, while the length of rod section 138'' is only slightly greater than the overall thickness of cap 80''. As a result, shoulder 141'' and flange 142'' engage opposite sides of cap 80'', thereby preventing rod 100'' from moving axially relative to cap 80'', and vice versa. Hence, if rod 100'' is inserted into tube housing 106'' and tube 102'', and that resulting subassembly is then inserted into the insulator housing via its open end, and thereafter the reduced diameter plug section 92'' of cap 80'' is secured in the circularly curved section 44'' of the insulator housing 42'', rod 100'' will be fixed relative to the insulator housing while tube housing 106'' and tube 102'' will be free to move axially relative to the rod and the insulator housing to the extent permitted by the difference in the length of tube housing 106'' and the distance between end cap 80'' and the junction of bore sections 60'' and 62''.

Looking now at Figs. 10''-14'' and 17'', rod 100'' has a knurled section 146'' which is slightly larger in diameter than its section 134'' and is sized to accommodate a helical gear 148'' having a center hole 149''. The latter may be affixed to rod 100'' by a press fit with knurled surface 146'', or by means of a suitable cement or other fixing agent, e.g., an epoxy cement. Gear 148'' may be made of a metal or a plastic. Rod 100'' is preferably made of metal for electrical conduction purposes. The preferred mode of mounting helical gear 148'' to the drive rod is by way of a friction fit, augmented by a suitable cement. Gear 148'' has evenly shaped, helically-directed gear teeth 150''. Gear 148'' is sized so that a portion of its periphery projects through aperture 110'' in tube housing 106'' for engagement of its teeth 150'' by the rotation trigger member 12'' (Figs. 10'', 17'' and 27'').

Trigger member 12'' has an elongate hole 154'' for accommodating pivot pin 36''A. Additionally, one end of that rotation trigger is provided with a plurality of helically pitched teeth 156'' which are shaped and sized to mate with teeth 150'' of gear 148''. The opposite end of the trigger member is preferably knurled or formed with grooves 160'' to eliminate slippage between the rotation trigger member and the surgeon's finger used to operate that trigger member. Trigger member 12'' also has an extension 162'' provided with a small aperture 164'' which is sized to accommodate one end of a tension spring 166''. The opposite end of the spring is formed with a circular extension sized to fit over pin 34''A of the left handpiece 16''L. Pivot hole 154'' is elongated so as to facilitate operation of the rotation trigger. When the latter is mounted to pin 36''A, spring 166'' exerts a force that normally holds the rotation trigger in its forward and down position (Fig. 10''), with its teeth 156'' being out of engagement with gear 148''. When that trigger is pulled back by a finger of the operating surgeon, its moves upwardly on pivot pin 36''A and also rotates on that pin, causing its teeth 156'' to engage and rotate helical gear 144'', thereby causing rotation of drive rod 100''. Rotation of trigger 12'' is limited in one direction by its engagement with the surface 57'' defining the forward

end of slot 56'' of the insulator housing 42'', and in the other direction by its engagement with shoulders 170''L and 170''R (Figs. 2'' and 3'') formed by handpieces 16''L and 16''R.

Referring now to Figs. 10'', 16'', 25'' and 26'', trigger member 10'' is preferably formed with an elongate aperture 180'' to accommodate a finger of the surgeon. Additionally, the trigger member has a hole 182'' to accommodate pivot pin 32''A on the left handpiece. The trigger member has a reduced thickness end portion 190'' that is provided with a rectangular notch 192'' that subdivides its upper end into two fingers 193'' and 195''. The notch and fingers are sized so as to make a pivotal connection with lug 112'' of tube housing 106''. It is to be noted that handpieces 16''L and 16''R have recesses 17''L and 17''R to accommodate the reduced thickness end portion 190'' of the trigger member. Trigger member 10'' is pivotally mounted so that its notch 192'' is engaged with lug 112''. Pivotal movement of trigger 10'' causes axial movement of tube housing 106'' and tube 104'' when the trigger member is pivoted toward and away from stationary handle 8''. Pivotal movement of trigger 10'' relative to the stationary handle 8'' is illustrated by the arrows in Fig. 1''. Pivotal movement of trigger 10'' causes the tube housing to move in insulator housing 42'' between a first rearward limit position (Fig. 1'') wherein tube housing 106'' is stopped by engagement with end cap 80'' and a second forward limit position wherein the distal (forward) end of the tube housing is blocked by the tapered bore section 62'' of the insulator housing.

Referring now to Figs. 10'' and 15'', the electrical terminal pin 7'' is made of metal and comprises a round pin section 210'' and an enlarged head section 212''. Preferably pin section 210'' is bifurcated as a result of a slot 214'' so as to be compressible radially when coupled to a mating female connector. Head section 212'' is generally round in cross-section except that it has diametrically opposed flat surfaces that mate with corresponding flat surface portions 25''A and 25''B (Fig. 2'') of cavities 24''L and 24''R. Pin 7'' also has a keyhole that extends perpendicular to its flat surfaces and

comprises an enlarged section 216'' and a reduced section 218''. The latter section has a radius of curvature larger than that of section 140'' but smaller than that of flange 142'' and rounded end 136'' of rod 100''. The enlarged section 216'' has a radius of curvature larger than the rounded end 136'' of rod 100''. A compression spring 222'' surrounds pin section 210'' in the hole formed by cavities 24''L and 24''R, being captivated between head section 212'' and the shoulder formed by the intersection of cavities 26''L and 26''R with cavities 24''L and 24''R respectively. Spring 222'' normally urges the terminal pin inwardly so as to have rod section 140'' locked in keyhole section 218''.

Referring now to Figs. 13''-15'' and 22'', tool head 6'' can take various forms. In this preferred embodiment of the invention, it takes the form of a releasable scissors-type head.

In this connection it should be noted that it is preferred to provide the outer tube or sleeve 102'' with a tubular sleeve-type bearing 230'' (Figs. 22'' and 24'') having a peripheral flange 232''. Bearing 230'' fits inside of and is bonded to tube 102'', with the distal end of the tube engaging peripheral flange 232'' as shown in Fig. 22''. Bearing 230'' may be made of TEFLON or some other commercially available material that has a relatively low coefficient of friction and the hardness required to withstand wear from repeated sliding contact with the tool head. The i.d. of bearing 230'' is slightly larger than the o.d. of rod 100'' and the o.d. of the body sections 250'' of scissors blade members 246''A and 246''B hereinafter described.

Referring now to Figs. 1'', 22''-24'' and 28''-30'', tool head 6'' is detachably secured to rod 100'' so as to be locked against rotational or axial movement relative to the rod. For this purpose, rod 100'' is provided with a tongue 240'' having an enlarged head 242'', with both the tongue and head having a pair of flat opposite surfaces 241'' and 243'' respectively. Tool head 6'' is preferably formed of two identical scissors blade members 246''A and 246''B formed of a stainless steel with spring-l. .e quality. Each blade member

comprises a body section 250'' that is semi-circular in cross-section, so as to have a flat face 252''. In addition, each body section is notched and its flat face 252'' is recessed as shown at 260'' and 262'' so that when the two faces are brought into confronting relation with one another, a bayonet slot 264'' is formed as shown in Fig. 28'' that is sized to mate with tongue 240'' of rod 100'' as shown in Fig. 22''.

Still referring to Figs. 22''-25'', blade members 246''A and 246''B are formed with spring arms 268'' that are integral with body sections 250'' and carry integral scissors blades 270''. Arms 268'' are formed so that in their normal state the scissors blades extend at an inclined angle to the longitudinal axes of body sections 250'' (Fig. 28''). An edge portion of each scissors blade is ground so as to provide a micropolished flat scissors face as shown at 272'' that terminates in a sharp edge 274''. Each scissors blade 270'' is formed so that it is bent longitudinally as viewed in Fig. 30'', so that its forward end or tip crosses the center axis of its associated body section 250''. Accordingly, when the two scissors blade members are secured together at their flat faces 252'' (Fig. 28'') by welding or other means, so as to form bayonet slot 264'', the scissors faces 272'' are engaged with one another at their proximal or rear ends (Fig. 30''), while their forward ends are separated (spaced apart) from one another (Fig. 28'') but extend laterally across the center axis of the tool head, i.e., across the planes of faces 252''. Consequently, if a radially-directed squeezing force is applied to blades 270'' normal to faces 252'' (as represented by the mutually-converging arrows in Fig. 28''), the blades will be forced together, and when that occurs, the resulting interference caused by the fact that the blades cross one another (as seen in Fig. 30'') will cause the blades to deflect back away from one another to an extent just sufficient to permit the sharp edges 274'' to close on one another in a scissors-like cutting action.

As seen in Fig. 22'', the scissors head 6'' is sized so that its body sections 250'' can slide within bearing sleeve 230''. Also, blades 270'' are sized so that they also can fit within and slide relative to bearing 230'' when

they are fully closed on one another.

Assembly of the tool involves several separately conducted subassembly procedures. The tool head 6'' is assembled by welding or brazing blade members 246''A and 246''B together. In a separate procedure, helical gear 148'' is mounted onto and secured to rod 100''. Then tool head 6'' is attached to rod 100'' by inserting the rod's tongue 240'' into bayonet slot 264''.

Contemporaneously, or before or after the foregoing steps, tube 102'' is affixed to tube housing 106'', and tubular sheath 104'' is affixed to insulator housing 42''. Thereafter, rod 100'', with tool head 6'' attached, is inserted into the proximal (rear) end of tube housing 106'' and forced forwardly so as to cause the scissors blade arms 268'' to yield enough to allow scissors blades 270'' to close on one another enough to permit the tool head to pass through tube 102'' and bearing 230'', and also to locate gear 148'' in bore section 122''. The diameter of bore section 122'' is slightly oversized with respect to helical gear 148'' so as to permit the gear to rotate therein. Thereafter, or before insertion of rod 100'' into the tube housing, end cap 80'' is mounted onto rod 100'' as previously described. In this connection, it is to be noted that the semi-circular hole 90'' in cap 80'' is slightly larger than the diameter of rod section 138'', while preferably the width of slot 88'' in cap 80'' is slightly smaller than the diameter of rod section 138'', with the result that the end cap makes a snap fit with the drive rod. Molded cap 80'' has flexibility that permits it to yield enough to allow rod 100'' to be forced through slot 88'' into hole 90''.

Thereafter, the subassembly consisting of tube 102'', tube housing 106'', rod 100'' with gear 148'', and tool head 6'', is slipped into the proximal (rear) end of insulator housing 42'', with the internal rib 78'' of the insulator housing being aligned and disposed in groove 116'' and slot 114'' of the tube housing. This step involves inserting tube 102'' into sheath 104'' so that blades 270'' can project from the forward (distal) end of the sheath. When the subassembly consisting of tube 102'', tube housing 106'', etc., is inserted into the insulator

housing, it is preferred that rod 100'' be withdrawn enough in tube housing 106'' (as viewed in Figs. 10'' and 22'') to permit sleeve bearing 230'' to surround scissors blades 270'' and thereby apply a radially directed compression force that holds the blades in closed position. Having the scissors blades closed by bearing 230'' facilitates insertion of the blades and tube into sheath 104''. Thereafter rod 100'' is shifted axially so as to permit end cap 80'' to be seated in the rear end of the insulator housing, and end cap 80'' is secured to that housing by a suitable cement or by ultrasonic welding as previously described. The internal rib 78'' in insulator housing 42'' cooperates with groove 116'' and slot 114'' to insure that the aperture 110'' of the tube housing is in confronting alignment with the trigger member 10'' when subsequently the resulting assembly is mounted to the handle assembly.

The foregoing combined subassemblies consisting of insulator housing 42'' and its attached sheath 104'', and tube housing 106'' and its associated parts, is then combined with the handle assembly. The latter may be preassembled by starting with left handpiece 16''L and first mounting trigger member 10'' on pivot pin 32''A. Simultaneously, or before or after the foregoing step, the rotational trigger 12'' is placed onto the post 36''A with its teeth engaged with helical gear 148'', and the spring 166'' attached thereto is subsequently attached to the post 34''A. Then terminal pin 7'', with compression spring 222'' mounted thereon, is placed into cavities 24''L and 26''L, with spring 222'' being compressed so as to provide a force urging pin 7'' inwardly (downwardly as viewed in Fig. 10''). Then the right handpiece 16''R is placed over the foregoing assembly into engagement with the left handpiece 16''L and the two handpieces are secured together by a suitable cement or by ultrasonic welding.

The handle assembly is attached to the assembly consisting of insulator housing 42'' and tube housing 106'', etc. by the simple expendent of inserting the insulating housing into the front end of the chamber formed by cavities 20''L and 20''R. When this is done, the rounded rear end of rod 100''

engages the small keyhole section 218'' and coacts with the edge of that keyhole section to cam pin 7'' outwardly enough to align the enlarged keyhole section 216'' with the rod, thereby allowing rod section 140'' to be forced into alignment with the pin, whereupon spring 222'' will force the pin inwardly again to lock rod 100'' to the terminal pin, in turn locking the insulator housing to the handle assembly.

It is to be noted that when inserting the insulator housing into the handle assembly, the trigger 10'' must be pulled back to its rear limit position as shown in Fig. 10'' so as to permit the insulator housing 42'' and cap 80'' to clear the finger section 193'' of the trigger, but the finger section 195'' projects up far enough to intercept the lug. Thereafter, assuming that the insulator housing has been locked to the handle assembly, reverse movement of the trigger back to the position of Fig. 1'' will cause finger section 193'' to engage the lug and thereby move the tube housing rearwardly in the insulator housing.

As mentioned hereinabove, the elongate pivot hole 154'' of the rotational trigger is sized so that spring 166'' will hold it in a down and forward position (Fig. 10''), in which position its teeth 156'' do not protrude into the insulator housing far enough to intercept gear 148'' and thus interfere with its axial movement when the tool assembly comprising the insulator housing and tube housing 106'' is inserted into or pulled out of the handle assembly. To further facilitate detachment of the tool assembly from the handle assembly, the slot 114'' in tube housing 106'' is sized so as to provide clearance with trigger teeth 156'' as the housing is inserted into or removed from the handle housing 16''L,16''R.

Operation of the tool is as described hereinafter. When trigger member 10'' is in its forward limit position (Fig. 1''), tube housing 106'' and tube 102'' are in their withdrawn or retracted position wherein bearing 230'' terminates short of engagement with the blades 270'' of tool head 6'', with the result that the blades are in their separated or open position (Figs. 1'', 22'' and 28''). When trigger member 10'' is pulled toward fixed handle 8'' to its other

limit position (Fig. 10''), the pivotal connection between the trigger member and lug 112'' of tube housing 106'' causes the latter to be moved forward in housing 42'', causing tube 102'' to telescope forwardly and causing bearing member 230'' to slip over and compress scissors blades 270'' into closing position.

The angular orientation of scissors blades 230'' relative to the handle assembly can be varied by manipulation of rotational trigger member 12''. When trigger member 12'' is pulled back, its gear teeth cause helical gear 148'' to rotate, thereby rotating rod 100'' and the tool head counterclockwise (as viewed in Fig. 17'') relative to the fixed handle member 8''. Because trigger member 12'' has only a limited number of teeth, it must be retracted and then released several times in order to rotate the tool head 360°. By way of example but not limitation, the number of teeth on rotational trigger 12'' and the number of teeth and the pitch thereof on helical gear 148'' may be set so that trigger 12'' must be pulled back and released approximately 8'' times in order to achieve a 360° rotation of the tool head.

The preferred tool design described above offers a number of advantages. For one thing, the tool comprises several discrete lower tier subassemblies plus two discrete higher tier or major subassemblies, one of the major subassemblies being a multi-component handle assembly and the other comprising insulator housing 42'', sheath 104'', cap 80'', tube housing 106'', tube 102'', rod 100'', helical gear 148'' and tool head 6'', with the latter major subassembly being releasably secured to the handle assembly. Detachment of this higher tier or major subassembly from the handle assembly is achieved by pulling the terminal pin outwardly (upwardly as viewed in Fig. 10'') so as to align the enlarged portion 216'' of its keyhole with the rounded head 136'' of rod 100'', thereby allowing the handle assembly to be pulled free of rod 100''. As a result, the major subassembly comprising insulator housing 42'', sheath 104'', cap 80'', tube housing 106'', tube 102'', rod 100'', helical gear 148'' and tool head 6'' can be replaced by a new nd like substitute subassembly.

In other words, the handle assembly is reusable with different substitute tool assemblies.

A second advantage resides in the fact that the scissors head shown in the drawings is removable from rod 100''. A third advantage is that different tool heads may be used in place of the scissors head shown in the drawings. Thus, for example, the tool head may be a grasper head comprising a pair of jaws with confronting serrated surfaces that can be forced together by forward movement of tube 102'' into grasping relation with tissue at a surgical site. The tool head also may comprise a combination grasper/cutter with one of the confronting faces of the two jaws having a cutting blade that is received in a notch in the other jaw. Another possibility is a tool head with cooperating members for holding a suture or a needle.

A fourth advantage resides in the fact that cap 80'' need not be cemented to the insulator housing. Instead, as shown in dotted lines in Fig. 9'', the cap could be provided with a peripheral groove 93'' in its reduced section 92'' and the insulator housing may be formed with an internal circumferentially-extending rib (not shown) sized to make a snap fit in groove 93'', thereby permitting the cap to be releasably interlocked with the insulator housing. If such arrangement is adopted, the cap may be easily detached from the insulator housing out of connection with rod 100'', thereby permitting the rod and its attached tool head to be withdrawn rearwardly out of tube 102'' and insulator housing 42''. This alternative embodiment facilitates removal and replacement of the subassembly consisting of rod 100'', helical gear 148'' and the tool head 6'', or simply of replacement of the tool head 6''.

A further advantage resides in the fact that the rotational trigger permits the surgeon to rotate the scissors blades relative to the handle assembly by a precise amount, thereby avoiding the need to rotate the handle assembly to achieve a particular cutting orientation of the scissors blades. The latter advantage is beneficial to the surgeon from the standpoint of comfort and ease of manipulation and ease of operation.

Still another advantage resides in the fact that bearing sleeve 230'' applies a like force to each of the two scissors arms 268'', with the force being distributed evenly about the circumference of the curved outer surfaces of scissors arms 268''. Bearing 230'' coacts with scissors arms 268'' to urge blades toward one another as they are forced to close on one another.

A particularly significant advantage of this invention resides in the fact that rod 100'' is stationary and surrounding tube 102'' is reciprocated by manipulation of trigger member 10''. This invention recognizes that surgeons need a point of reference in order to determine if and when they are moving a surgical scissors relative to the surgical site. In the absence of sheath 104'', movement of outer tube 102'' as seen by the surgeon might have a tendency to confuse the surgeon into believing that the tool is moving axially relative to the patient. The provision of outer sheath 104'' eliminates the possibility of such confusion. Since sheath 104'' is at least coextensive with tube 102'' (and preferably projects slightly forward of tube 102'' even when the tube is moved to its forwardmost position relative to rod 100'') and hence conceals any axial movement of that tube relative to handle assembly 2'', manipulation of handle members 8'' and 10'' causing the jaws to open and close is accomplished without the surgeon realizing that there is actual axial movement of tube 102''. Instead, the surgeon sees that sheath 104'' is stationary, with the result that the surgeon is free to concentrate his attention on the actual position of the scissors blades 230'' (the latter do not appear to move toward and away from the patient when the jaws are opened or closed, unless the surgeon actually moves the tool relative to the patient).

Still another significant advantage is that the tool described above is adapted to conduct monopolar cauterization, but also may be used without being electrified. If the tool is to be made for noncauterization uses, pin 7'' need not be an electrically conductive element and instead may function simply as a locking device for rod 100'' as hereinabove described.

Other advantages will be obvious to persons skilled in the art.

Persons skilled in the art will also appreciate that the invention is susceptible to various modifications. Thus, as noted above, various forms of tool heads may be used in practicing the invention. Also the tool head 6'' may be permanently secured to the rod 100''. Additionally, the manner of connecting various components may be varied. Thus, the proximal (rear) end of tube 102'' may be externally threaded to mate with an internal thread formed in the bore section 128'' of tube housing 106''. Also, the insulator sheath 104'' may be formed of a material which is sufficiently rigid to permit it to be formed with an external screw thread, thereby permitting it to mate with a cooperating internal thread formed in bore 66'' of insulator housing 42''. A further possible modification resides in the fact that a different tool head may be attached to the operating rod 100''. For example, the tool head may comprise a grasper arrangement, e.g., a grasper arrangement as disclosed in U.S. Patent No. 3'',404'',677'', issued October 8'', 1968'' to H.A. Springer for "Biopsy And Tissue Removing Device".

Fig. 31'' shows another modification of the invention wherein a compression spring 290'' is mounted on rod 100'' between the forward end of tube housing 106'' and the tapered bore section 162'' of insulator housing 42''. Spring 290'' urges tube housing 106'' rearwardly in the insulator housing so that it is intercepted by cap 80'', in which position the tube housing holds trigger member 10'' in its forward (open) position as shown in Fig. 1''.

Still another possible modification is to provide a different form of pivotal connection between trigger 10'' and tube housing 106''. Thus, for example, tube housing 106'' could be provided with a radially-extending external projection having a pivot hole, and trigger member 10'' could be provided with a pivot hole designed to mate with the pivot hole on the external extension of the tube housing, with a separate pivot pin being inserted into the mating pivot holes and secured in place so as to pivotally connect the trigger to the extension on the tube housing.

Still another possible modification involves connection of the electrical

terminal pin to drive rod 100''. It is envisioned that the proximal (rear) end of rod 100'' may be provided with a threaded axially extending hole, and the terminal pin may be attached to rod 100'' by providing the terminal pin with an externally-threaded front end that screws into the tapped hole in the end of the rod. In such event, the terminal pin may extend parallel rather than at a right angle to the longitudinal axis of the insulator housing. A further possibility is to use a separate electrically conductive screw to secure the conductive terminal pin to the threaded axially extending hole in the rear end of rod 100''.

Another contemplated modification is to provide a scissors head wherein the two blade members 246''A and 246''B are not permanently secured together by welding or brazing but instead are releasably or permanently affixed in an adapter member (not shown) that is designed to mate with the forward end of rod 100''. The adapter may be releasably or permanently cocupled to the rod.

In yet another contemplated modification, and looking now at Fig. 32'', a novel tool head 400'' is shown coupled to rod 100'' for use in tying off suture ends extending away from a surgical site.

Novel tool head 400'' is shown in greater detail in Figs. 33''-36''. Novel tool head 400'' generally comprises means for running suture throws toward a surgical site so as to form a knot and means for severing the suture ends extending away from the knot. More particularly, novel tool head 400'' is preferably formed out of two scissor members 500'' (see Figs. 33''-39'') and 600'' (see Figs. 33''-36'' and 40''-42'') which preferably are made of a suitable metal such as stainless steel.

Looking now at Figs. 33''-39'', first scissor member 500'' comprises a rod engaging portion 502'', a sleeve engaging portion 504'', an elastically flexible portion 506'', a substantially rigid blade portion 508'', and a suture throw rundown element 510''.

Looking now at Figs. 37''-39'', rod engaging portion 502'' has a semi-

cylindrical cross-section comprising a flat inner surface 512'' and a semi-circular outer surface 514''. A distal portion 516'' is disposed between and connects rod engaging portion 502'' and sleeve engaging portion 504''. Distal portion 516'' has a semi-cylindrical cross-section and is sized so as to have a semi-circular outer surface 518'' that is smaller in diameter than the diameter of rod engaging portion 502''.

Sleeve engaging portion 504'' also has a semi-cylindrical cross-section. It comprises a flat inner surface 520'' and a semi-circular outer surface 522''. Flat inner surface 520'' is substantially coplanar with flat inner surface 512'' of rod engaging portion 502''. Semi-circular outer surface 522'' has a diameter that is larger than the diameter of rod engaging portion 502''.

Elastically flexible portion 506'' extends from and is connected to the distal end of sleeve engaging portion 504''. It is normally outwardly and distally curved relative to sleeve engaging portion 504'', as seen in Fig. 33''. Elastically flexible portion 506'' comprises a semi-cylindrical cross-section that is smaller than the cross-section of sleeve engaging portion 504''. Elastically flexible portion 506'' connects sleeve engaging portion 504'' to rigid blade portion 508''.

Rigid blade portion 508'' comprises a substantially semi-cylindrical shape, so as to have a semi-circular outer surface 524'' and a flat inner surface 526''. Semi-circular outer surface 524'' further includes a substantially flattened portion 528'' defining a cutting edge 530''. Cutting edge 530'' is adapted for bearing against a similar cutting edge 630'' located on second scissor member 600'' as will hereinafter be described in further detail.

A connector portion 532'' extends distally from rigid blade portion 508'' and connects the latter to suture throw rundown element 510''. Connector portion 532'' has a frustoconical shape adapted to interconnect the distal portion of rigid blade portion 508'' with the proximal portion of suture throw rundown element 510''.

Suture throw rundown element 510'' comprises a semi-frustoconical wall

534'' having a curved inner surface 536'' and a curved outer surface 538''. Wall 534'' has a cylindrical bore 540'' that extends between inner surface 536'' and outer surface 538''. Bore 540'' is disposed at an angle relative to inner and outer surfaces 536'' and 538'' and is spaced from the distal end 542'' of first scissor member 500''.

Second scissor member 600'' (see Figs. 33''-36'' and 40''-42'') is essentially identical to first scissor member 500'', except as hereinafter described in detail. More particularly, second member 600'' comprises a rod engaging portion 602'', a sleeve engaging portion 604'', an elastically flexible portion 606'', a substantially rigid blade portion 608'', and a suture throw rundown element 610''.

Looking now at Figs. 40''-42'', rod engaging portion 602'' has a semi-cylindrical cross-section comprising a flat inner surface 612'' and a semi-circular outer surface 614''. A distal portion 616'' is disposed between and connects rod engaging portion 602'' and sleeve engaging portion 604''. Distal portion 616'' has a semi-cylindrical cross-section and is sized so as to have a semi-circular outer surface 618'' that is smaller in diameter than the diameter of rod engaging portion 602''.

Sleeve engaging portion 604'' also has a semi-cylindrical cross-section. It comprises a flat inner surface 620'' and a semi-circular outer surface 622''. Flat inner surface 620'' is substantially coplanar with flat inner surface 612'' of rod engaging portion 602''. Semi-circular outer surface 622'' has a diameter that is larger than the diameter of rod engaging portion 602''.

Elastically flexible portion 606'' extends from and is interconnected to the distal end of sleeve engaging portion 604''. It is normally outwardly and distally curved relative to sleeve engaging portion 604'', as shown in Fig. 33''. Elastically flexible portion 606'' comprises a semi-cylindrical cross-section that is smaller than the cross-section of sleeve engaging portion 604''. Elastically flexible portion 606'' connects sleeve engaging portion 604'' to rigid blade portion 608''. Rigid blade portion 608'' comprises a substantially semi-

cylindrical shape, so as to have a semi-circular outer surface 624'' and a flat inner surface 626''. Semi-circular outer surface 624'' further includes a substantially flattened portion 628'' defining a cutting edge 630''. Cutting edge 630'' is adapted for bearing against the similar cutting edge 530'' located on first scissor member 500'' as previously described.

A connector portion 632'' extends distally from rigid blade portion 608'' and connects the latter to suture throw rundown element 610''. Connector portion 632'' has a frustoconical shape adapted to interconnect the distal portion of rigid blade portion 608'' with the proximal portion of suture throw rundown element 610''.

Suture throw rundown element 610'' comprises a semi-frustoconical wall 634'' having a curved inner surface 636'' and a curved outer surface 638''.

Suture throw rundown element 610'' differs from suture throw rundown element 510'' in that a slot 650'' and a bore 652'' are substituted for the bore 540''.

More particularly, a slot 650'' extends into a portion of the suture throw rundown element's distal end 642''. Slot 650'' intersects a bore 652'' that extends through sidewall 634'' of suture throw rundown element 610''. Thus, outer surface 638'' of suture throw rundown element 610'' communicates with inner surface 636'' via slot 650'' and bore 652''. Slot 650'' and bore 652'' are aligned with one another lengthwise of rundown element 610''. In addition, tool head 400'' is constructed so that bore 652'' of suture throw rundown element 610'' will be generally aligned diametrically with bore 540'' of suture throw rundown element 510'' when the two suture throw rundown elements abut one another as shown in Figs. 35'' and 36''. Suture throw rundown element 610'' is bevelled on its inner surface around hole 652'' and along slot 650'', as shown at 654''.

Looking next at Figs. 34''-36'', when tube 102'' is in its second extended position, the first and second scissor members 500'' and 600'' will be located substantially adjacent to one another such that the inner surfaces

526'' and 626'' of their respective rigid blade portions 508'' and 608'' will engage one another. In addition, the suture throw rundown elements 510'' and 610'' will substantially abut one another so as to form a generally cylindrical axially-extending cavity 402'' (Fig. 35'') defined by the union of curved inner surface 536'' of suture throw rundown element 510'' and the curved inner surface 636'' of suture throw rundown element 610''.

Tool head 400'' is assembled to rod 100'' as follows. Rod 100'' comprises a distally facing cavity 199'' (Figs. 33'' and 34'') located at its distal end. Cavity 199'' corresponds in size and shape to the size and shape of rod engaging portions 502'' and 602'' when those portions are in aligned, abutting relationship with one another, as shown in Figs. 33'' and 34''. Also, when rod engaging portions 502'' and 602'' are in aligned, abutting relationship with one another, surfaces 512'' and 612'' are also in abutting relationship. Thus, first scissor member 500'' and second scissor member 600'' may be coupled to rod 100'' by locating their rod engaging portions 502'' and 602'' within rod cavity 199'' at the distal end of rod 100'', and thereafter securing them in place by welding or other suitable attachment means. They also may be attached by a press fit.

As a consequence of the foregoing attachment operation, sleeve engaging portions 504'' and 604'' will also be aligned with one another such that flat surfaces 520'' and 620'' abut one another. In this configuration, sleeve engaging portions 504'' and 604'' will together define a generally cylindrical structure. Outer surfaces 522'' and 622'' of the aligned sleeve engaging portions 504'' and 604'' slidably engage the tubular sleeve-type bearing 230'' (see Figs. 33'' and 34'') which is located adjacent to the inner proximal end of tube 102'', as previously disclosed.

Accordingly, when tube 102'' is moved from its first retracted position (Fig. 33'') to its second extended position (Figs. 34'' and 35''), tubular sleeve-type bearing 230'' will first slidingly engage outer surfaces 522'' and 622'' of first and second scissor members 500'' and 600''. As tube 102'' continues to

move distally, tubular sleeve-type bearing 230'' will then radially compress elastically flexible portions 506'' and 606'' toward one another, so as to cause cutting edges 530'' and 630'' to close on one another in a scissors action. Once tube 102'' is in its fully extended second position (see Fig. 35''), suture throw rundown elements 510'' and 610'' combine to form a unified assembly. When tube 102'' is thereafter moved from its second extended position (Figs. 34'' and 35'') to its first retracted position (Fig. 33''), first and second scissor members 500'' and 600'' will automatically return to the position shown in Fig. 33''.

If desired, a locking pin 700'' (see Fig. 32'') may be provided in handle 8'' to releasably engage a bore 702'' formed in trigger 10'' so as to releasably hold novel tool head 400'' in its closed position when desired.

Referring now to Figs. 43''-49'', one preferred method for tying off suture with the apparatus of the present invention comprises the steps of:

(1) forming a suture throw 800'' in the suture ends 802'' and 804'' extending away from tissue 900'' which is located at a surgical site (Fig. 43'');

(2) with the surgical instrument's tube 102'' in its first retracted position, threading suture end 802'' through bore 540'' in first scissor member 500'' (Fig. 44'');

(3) sliding the other suture end 804'' through the second scissor member's slot 650'' and into its bore 652'', and moving the surgical instrument's tube 102'' to its second extended position so as move the scissor members into their closed position (Fig. 45'');

(4) while holding suture ends 802'' and 804'' taut, running suture throw 800'' down the lengths of suture toward tissue 900'' by moving the surgical instrument toward the tissue (Fig. 46'');

(5) moving the surgical instrument's tube 102'' to its first retracted position while holding the tool stationary relative to the surgical site, thereby allowing the first and second scissor members 500'' and 600'' to move elastically away from each other and to pull the suture throw 800'' tight at

tissue 900'' (Fig. 47'');

(6) disengaging suture ends 802'' and 804'' from the surgical instrument by pulling the instrument back from the surgical site;

(7) with the surgical instrument's tube 102'' in its first retracted position so that scissor members 600'' and 500'' are in open position, positioning the surgical instrument adjacent to the suture ends 802'' and 804'' (Fig. 48''); and

(8) moving tube 102'' from its first retracted position to its second extended position, thereby causing cutting blades 530'' and 630'' to be brought against one another and thereby sever the suture ends 802'' and 804'' with a scissor-type action (see Fig. 49'').

In the usual course of practicing the invention, steps 1''-6'' may be repeated several times before step (7) to form a desired knot adjacent tissue 900''.

The Combined Bone Anchor, Suture Grasper and Suture Throw Rundown Device

According further embodiments of the invention, a bone anchor, suture grasper and/or suture throw rundown device are combined in a surgical kit for use in repairing and/or reattaching soft tissue, e.g., via endoscopic surgical methods. Such kits, combining any combination of the foregoing, are sterilized and packaged in a conventional manner known in the art.

According to a related embodiments of the invention, a surgical method for repairing and/or reattaching soft tissue, e.g., endoscopically, combines bone anchoring technique, suture grasping and/or suture throw rundown technique as described above.

Those skilled in the art will readily appreciate advantages of combining the devices and techniques described herein. For example, following insertion of a bone anchor as describe above, a suture grasper can be utilized to tension any suture emanating therefrom and, thereby, more firmly affix the anchor in the bone.

Conclusion

Described above is are improved surgical systems and methods meeting the objects set forth herein. Numerous changes, alterations, variations, and modifications may be made to the foregoing embodiments without departing from the scope of the present invention.

Thus, for example, the shaft subassembly may include a lumen having an elliptical cross-section, rather than a circular transverse cross-section, in order to better accommodate wire-like elements 402' (see Fig. 58'). Further, instead of locating the outwardly flaring portions of the wire-like elements 402' in the same plane, those portions may be located in adjacent parallel planes (see Fig. 59'). Still further, instead of utilizing one wire-like element 402' with a hook at its distal end and another wire-like element 402' without a hook at its distal end, a single wire-like element 402' having a hook at its distal end might be used (see Fig. 60'). Similarly, each wire-like element 402' may be hooked at its distal end (see Fig. 61'), and the lengths of the wire-like elements may be selected such that the hooks overlap one another during closure (see Fig. 62'), or such that the hook of one wire-like element resides within a projection of the area enclosed by the hook of the other wire-like element during closure (see Fig. 63'). In addition, small ball-like enlargements 800' may also be placed at the ends of the wire-like elements 402'. These enlargements 800' will help prevent the wire-like elements from spearing any braided suture or tissue which may be engaged by the tips of the wires.

In addition, the actuation means may also be provided with an electrical connection 802' (see Fig. 33') at the closed end of its housing 704'. In that case, proximal end 524' of shaft subassembly 500' would engage electrical connection 802', and shaft 502' and outer housing 604' of the grasper assembly and housing 704' of the actuation means 305' would be formed of insulating material. This alternative would allow the device to be used in cauterization procedures as well as in grasping and suturing

procedures.

It should be understood that various changes and modifications of the preferred embodiments may be made within the scope of the invention. Thus it is intended that all matter contained in the above description be interpreted in an illustrative and not limited sense.

In view of the foregoing, we claim:

1. A surgical system comprising

(a) a fastener for coupling an object to bone, comprising

an approximately cylinder shaped member of expandable material for insertion into an opening in a bone, the member including an outer surface having structure for expandable engagement with an inner surface of the bone opening, said expandable member having an axial channel defined therein extending at least partially between proximal and distal ends of said expandable member;

an elongated element for insertion into said expandable member, the insertion element including proximal and distal ends and a channel defined between said ends for engagement with a suture, said distal end of insertion element including a projection for expansion of the axial channel of said expandable member upon engagement of said proximal end of said insertion element with said axial channel of said expandable member whereby by insertion of said insertion element, expandable member is ineversibly expanded to obtain a pressure fit with said opening in said bone; and

(b) a device for grasping a filament-like object.

2. A surgical system comprising

(a) fastener for coupling an object to bone, comprising

an expandable member for insertion into an opening in a bone, the member including an outer surface for expandable engagement with an inner surface of the bone opening, said expandable member having an axial channel defined therein extending at least partially between proximal and distal ends of said expandable member, said distal end of said expandable member comprising means for axially releasing said expandable

member from a holding means;

an elongated element for insertion into said expandable member, the insertion element including proximal and distal ends;

a projection on an outer surface of said element for expansion of the axial channel of said expandable member upon engagement of said proximal end of said insertion element with said distal end of said expandable member, and

(b) a device for grasping a filament-like object.

3. A surgical system comprising

(a) a rivet for coupling an object to bone for use with an expandable member capable of insertion into an opening in a bone, the rivet comprising:

an elongated element for insertion into a distal end of said expandable member, the element having a shaft with proximal and distal ends, the distal end of said elongated element including a radially projection portion and an outer surface of said shaft including a radially outward projecting portion adapted to expand said expandable member;

a washer having upper and lower surfaces, said surfaces defining a bore therebetween, said bore disposed around a portion of the shaft of the elongated element, wherein said washer is adapted for movement independent of said elongated element, and

(b) a device for grasping a filament-like object.

4. A surgical system comprising

(a) an expandable member for use in a bone fastener, comprising

a substantially cylindrical outer surface for engagement

with an opening in a bone, said member having proximal and distal ends; said member having defined therein an axial channel extending at least partially between said ends and defining an inner surface of said member, said axial channel susceptible to enlargement by a compressive force acting substantially orthogonal to said inner surface of said expandable member;

a plurality of projections extending radially outwardly from said outer surface for contacting the bone within said opening upon enlargement of said channel; and

means engaged with said distal end of said expandable member for axially releasing said member from an elongated holder, and

(b) a device for grasping a filament-like object.

5. A surgery system comprising

(a) a first apparatus for use within an endoscope, comprising

an elongated, substantially hollow holding means for emplacing a bone fastener in a bone opening, said holding means having distal and proximal ends;

an expandable member having a proximal and a distal end integral with the proximal end of the holding means, said member comprising:

a substantially cylindrical outer surface for engagement with an opening in a bone;

an axial channel defined between said ends extending at least partially between said ends and defining an inner surface of said member, said axial channel having an inside diameter susceptible to enlargement by a compressive force acting substantially orthogonal to said inner surface of said

expandable member; and

a plurality of projections extending radially outwardly from said outer surface for contacting the bone within said opening, and

(b) a device for grasping a filament-like object.

6. A surgical system comprising

(a) an apparatus for placing a bone fastener in an opening in a bone, comprising

an expandable member with an axial channel defined therein;

an elongated, substantially hollow holder for the expandable member, the holder constructed to maintain the expandable member in position within the bone opening;

an element for engagement with an inner surface of the axial channel;

means intermediate the expandable element and holder for axially releasing said expandable member from said holder when said expandable element is fully expanded within said bone opening;

means adapted for co-axial movement relative to the holder for placing the element into the axial channel of the expandable member, and

means co-axially moveable within the hollow body for activating the means for axially releasing the expandable member from the holder, and

(b) a device for grasping a filament-like object.

7. A surgical system comprising:

an expandable member for insertion into an opening in a bone, the

member having an axial channel defined therein, an outer surface of the expandable member for engagement with an inner surface of the bone opening;

an element for insertion into said axial channel of said expandable member, said element including proximal and distal ends, said proximal end having a projecting surface for engagement with an inner surface of said axial channel;

a holder including a frangible membrane engaged with the distal end of said expandable member, the holder capable of maintaining the expandable member in position within the bone opening, and

a device for grasping a filament-like object.

8. A surgical system according to any of claims 1 - 7, wherein said device for grasping a filament-like object comprises

at least one wire-like element having a distal end, a proximal end, and object capturing means for capturing said object to said distal end;

a hollow shaft having a longitudinal axis, a distal end and a proximal end, said shaft being adapted to contain said at least one wire-like element; and

actuation means attached to said proximal end of said at least one wire-like element and to said proximal end of said shaft for (i) reciprocally moving said at least one wire-like element between a first position wherein said object capturing means are contained within said shaft and a second position wherein said object capturing means extend out of said distal end of said shaft, and (ii) rotating said at least one wire-like element and said shaft as a unit about said longitudinal axis of said shaft.

9. A surgical system according to any of claims 1 - 7, wherein said device for grasping a filament-like object comprises

a wire assembly comprising at least one wire-like

severing excess suture toward and away from one another, said mechanism including movable means in said tubular housing engaged and movable by said trigger member for causing said mechanism to move said portions of said means for running suture throws and said means for severing excess suture toward and away from one another in response to pivotal movement of said trigger assembly.

13. A surgical method, comprising

(a) providing an expandable member for insertion into an opening in a bone, the member having defined therein an axial channel having a diameter, said expandable member also including a means for axially releasing said expandable member from an emplacement means;

(b) engaging said expandable member at a distal end thereof by way of said emplacement means;

(c) inserting said expandable member into said soft tissue and bone while maintaining engagement with said distal end of the expandable member;

(d) applying a continuous, compressive force to said expandable member to expand the diameter of the axial channel so that an outer surface of said expandable member engages with the bone;

(e) activating the means for axially releasing, so that said expandable member is released from the emplacement means when the continuous force stops; and

(f) providing a device for grasping a filament-like object and using said device to suture said soft tissue.

14. A surgical method for repairing soft tissue, comprising

(a) providing an expandable member having a proximal end for insertion into an opening in a bone and a distal end integral with a holding means by way of a frangible membrane, the expandable member having an

axial channel of a certain diameter;

(b) inserting the expandable member into the opening by way of the holding means;

(c) inserting a proximal end of an elongated element into the axial channel of the expandable member at a distal end thereof, the element having a projecting portion;

(d) continuously, axially advancing the element into the axial channel so that the projecting portion of the element exerts a force substantially orthogonal to said axial channel and expands the diameter of the axial channel into the bone opening;

(e) disengaging the expandable member from the holding means by severing the frangible membrane, and

(f) providing a device for grasping a filament-like object and using said device to suture said soft tissue.

15. A surgical method according to any of claims 13 - 14, wherein step (f) comprises providing a device for grasping a filament-like object comprising:

at least one wire-like element having a distal end, a proximal end, and object capturing means for capturing said object to said distal end;

a hollow shaft having a longitudinal axis, a distal end, and a proximal end, said shaft being adapted to contain said at least one wire-like element; and

actuation means attached to said proximal end of said at least one wire-like element and to said proximal end of said shaft for (i) reciprocally moving said at least one wire-like element between a first position wherein said object capturing means is contained within said shaft and a second position wherein said object capturing means extend out of said distal end of said shaft, and (ii) rotating said at least one wire-like element and said shaft as a unit about said longitudinal axis of said shaft.

16. A surgical method according to claim 15, wherein step (f) further comprises: positioning said at least one wire-like element in said first position;

inserting said shaft through said tissue;

maneuvering said distal end of said shaft so that it is located substantially adjacent to said object;

positioning said at least one wire-like element in said second position, and maneuvering said object capturing means so as to substantially surround said object;

moving said at least one wire-like element toward said first position so as to grapple a portion of said object and thereby secure said object to said distal end of said shaft;

withdrawing said shaft from said tissue so as to thread said object through said tissue; and

positioning said at least one wire-like element in said second position, and maneuvering said shaft so as to cause said object capturing means to release said object.

17. A surgical method according to any of claims 13 - 14, comprising the step of running a surgical suture toward a surgical site to form a knot from a site remote therefrom.

18. A surgical method according to claim 17, wherein said running step comprises

(a) providing a surgical instrument comprising a tool head having first and second cooperating tool members movable between a first open position wherein they are spaced from one another and a second closed position wherein they are proximate to one another, said first and second tool members comprising first means for running surgical suture throws toward a surgical site and second means for severing excess lengths of suture adjacent

to said knot; and drive means for moving said first and second cooperating tool member between said first open position and said second closed position;

(b) forming a surgical throw in lengths of suture extending from a surgical site;

(c) with said tool members in said first open position, capturing one of said lengths of suture in said first tool member;

(d) moving said tool members to said second closed position and capturing the other length of said suture in said second tool member;

(e) while holding said lengths of suture taut, running said surgical throw toward said surgical site with said surgical instrument;

(f) moving said tool members to said first open position, thereby allowing said first and second members to pull said surgical throw tight;

(g) withdrawing said surgical instrument from the vicinity of said surgical site;

(h) disengaging said lengths of suture from said tool members;

(j) with said tool members in said first open position, locating said tool head in the vicinity of said surgical site such that said second means are located adjacent to the excess lengths of suture; and

(k) moving said tool members from said first open position to said second closed position, thereby causing said second means to sever said excess lengths of suture adjacent to said surgical knot.

19. A surgical method comprising:

providing a device for grasping any of a filament-like object and a suture object, said device including (i) at least one wire-like element having a distal end, a proximal end, and object capturing means for capturing said object in said distal end, and (2) a hollow shaft having a longitudinal axis, a distal end, and a proximal end, said shaft being adapted to contain said at least one wire-like element;

positioning said at least one wire-like element in a first position wherein said object capturing means is contained within said shaft,

inserting said shaft through said tissue;

maneuvering said distal end of said shaft so that it is located substantially adjacent to said object;

positioning said at least one wire-like element in a second position wherein said object capturing means extend out of said distal end of said shaft, and maneuvering said object capturing means so as to substantially surround said object;

moving said at least one wire-like element toward said first position so as to grapple a portion of said object and thereby secure said object to said distal end of said shaft;

withdrawing said shaft from said tissue so as to thread said object through said tissue;

positioning said at least one wire-like element in said second position, and maneuvering said shaft so as to cause said object capturing means to release said object; and

anchoring said object in a bone.

20. A surgical method according to claim 19, wherein said anchoring step includes the steps of

(a) providing an expandable member for insertion into an opening in a bone, the member having defined therein an axial channel having a

diameter, said expandable member also including a means for axially releasing said expandable member from an emplacement means;

(b) engaging said expandable member at a distal end thereof by way of said emplacement means;

(c) inserting said expandable member into said soft tissue and bone while maintaining engagement with said distal end of the expandable member;

(d) applying a continuous, compressive force to said expandable member to expand the diameter of the axial channel so that an outer surface of said expandable member engages with the bone;

(e) activating the means for axially releasing, so that said expandable member is released from the emplacement means when the continuous force stops.

21. A surgical method according to claim 19, wherein said anchoring step includes the steps of

(a) providing an expandable member having a proximal end for insertion into an opening in a bone and a distal end integral with a holding means by way of a frangible membrane, the expandable member having an axial channel of a certain diameter;

(b) inserting the expandable member into the opening by way of the holding means;

(c) inserting a proximal end of an elongated element into the axial channel of the expandable member at a distal end thereof, the element having a projecting portion;

(d) continuously, axially advancing the element into the axial channel so that the projecting portion of the element exerts a force substantially orthogonal to said axial channel and expands the diameter of the axial channel into the bone opening;

(e) disengaging the expandable member from the holding means by

severing the frangible membrane.

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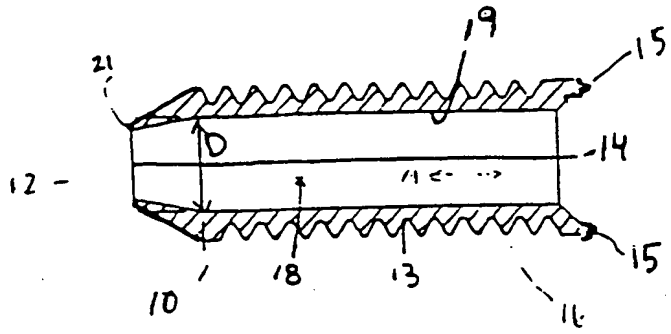

Fig 1

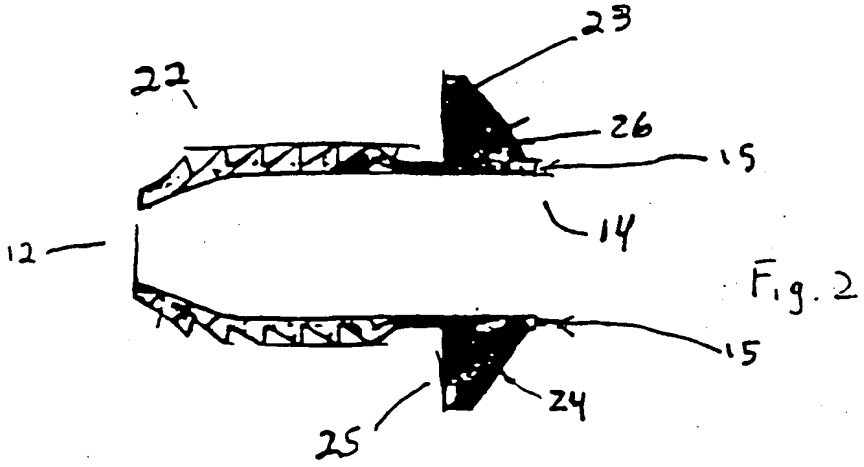

Fig. 2

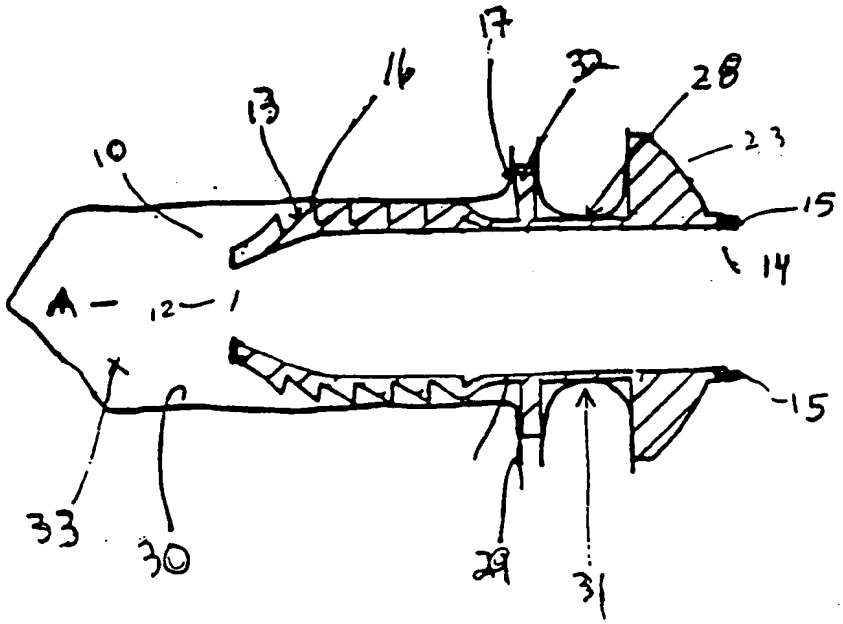

Fig. 3

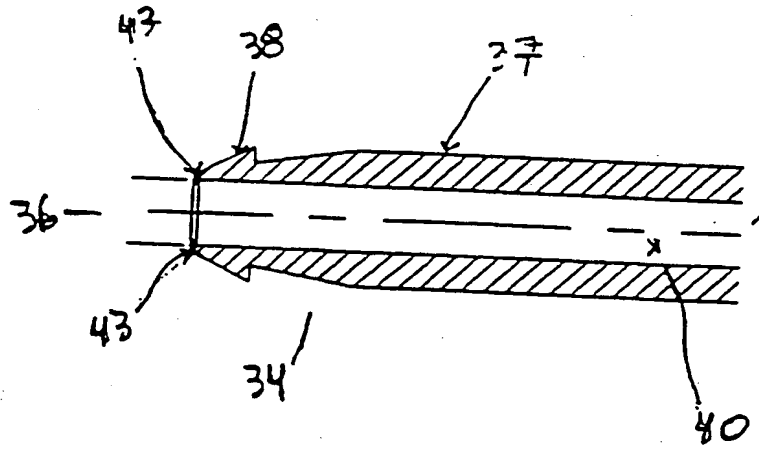

Fig. 4

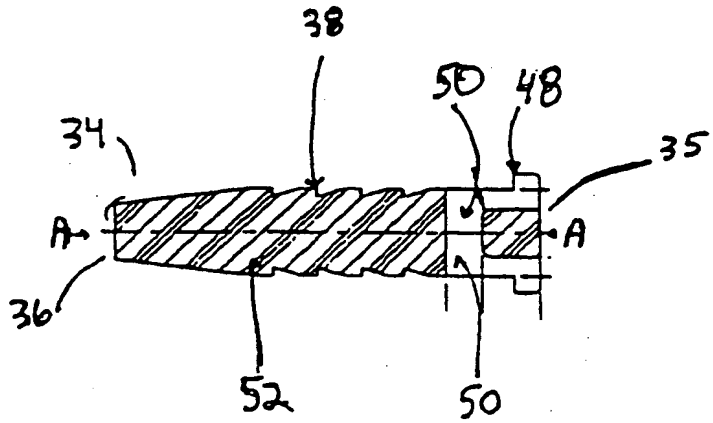

Fig. 5

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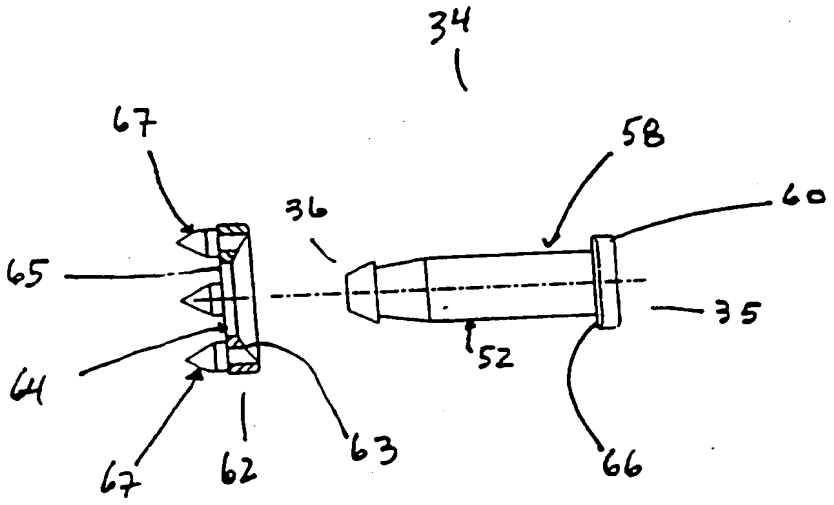

FIG. 6

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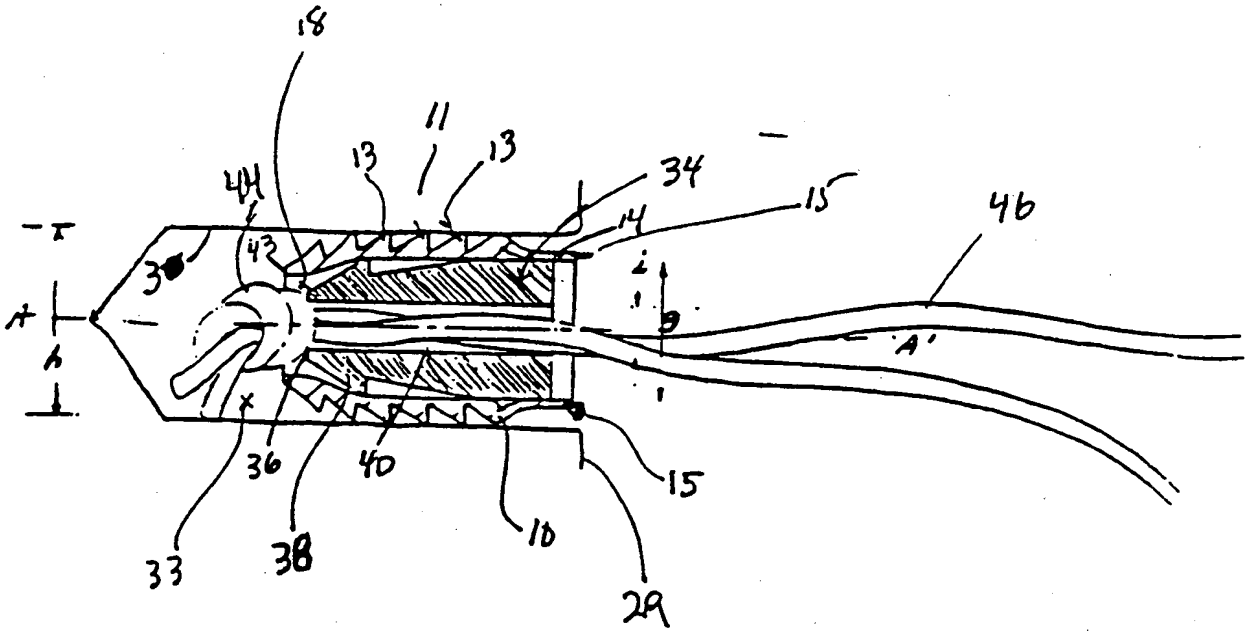

Fig. 7

5/80 Figure 8

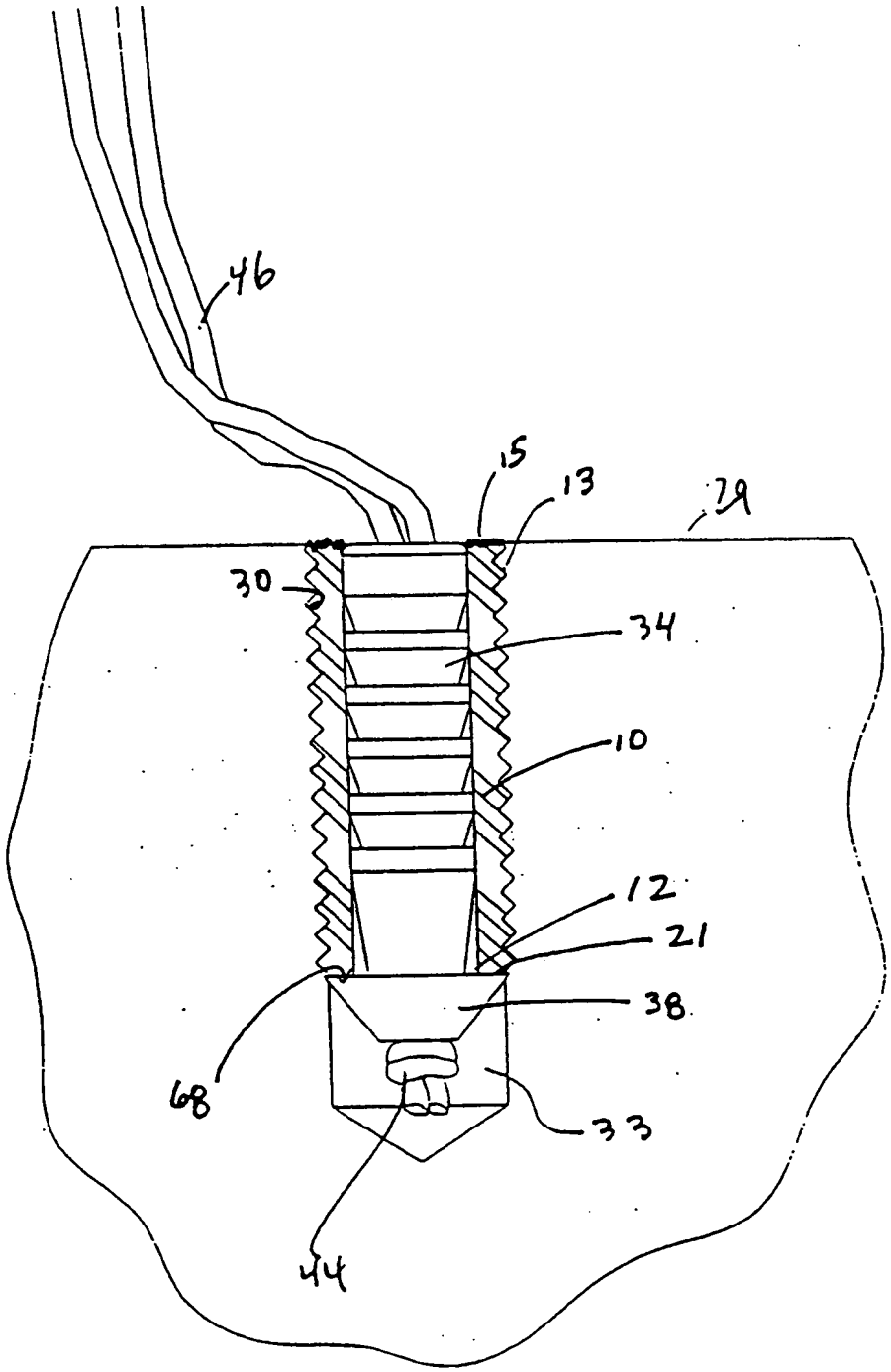

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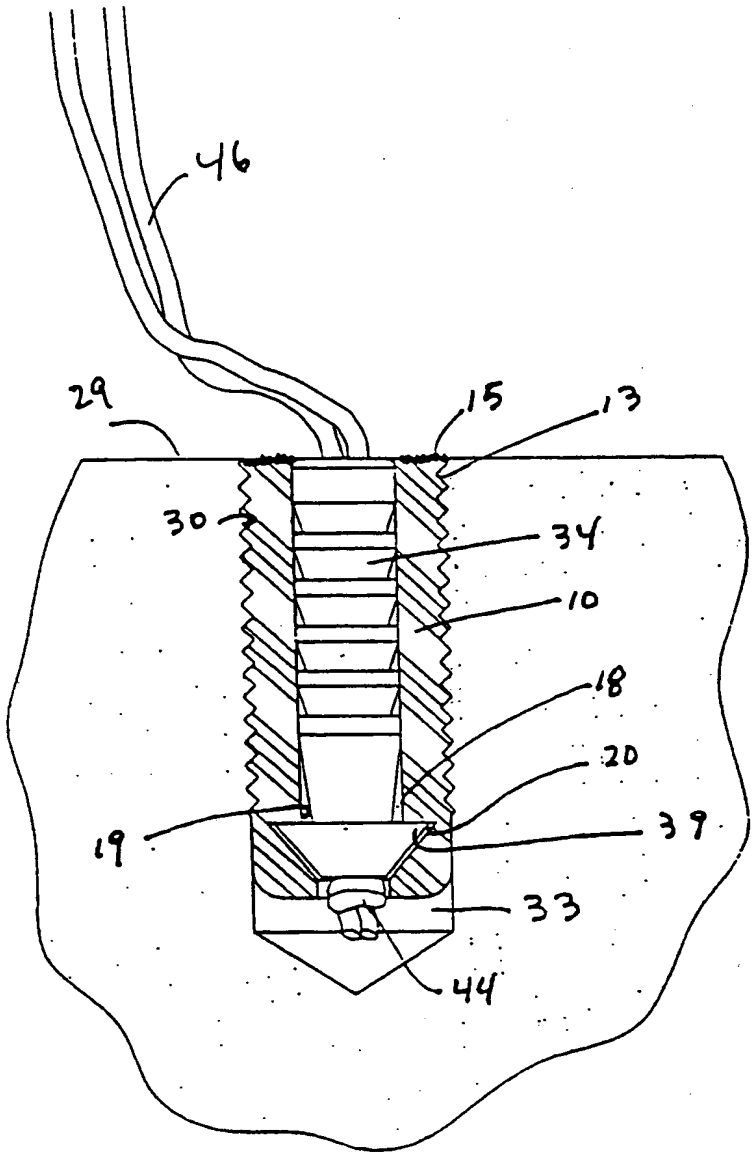
Figure 9



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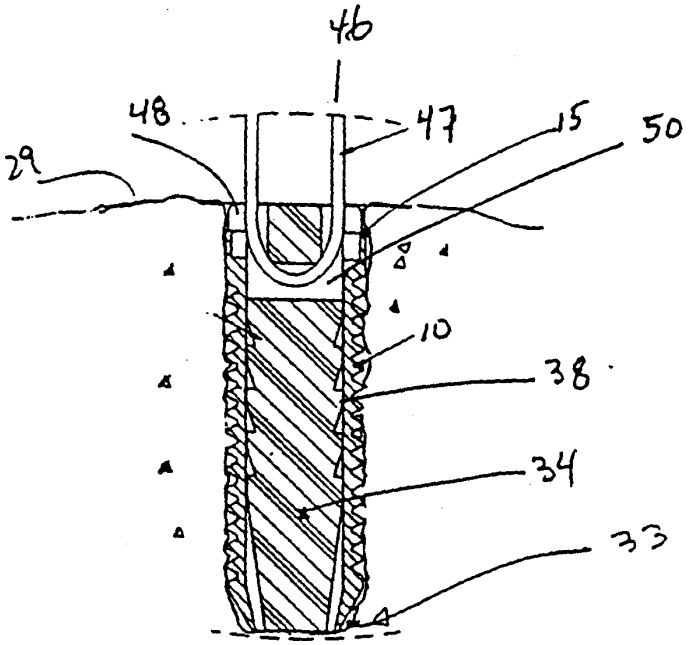
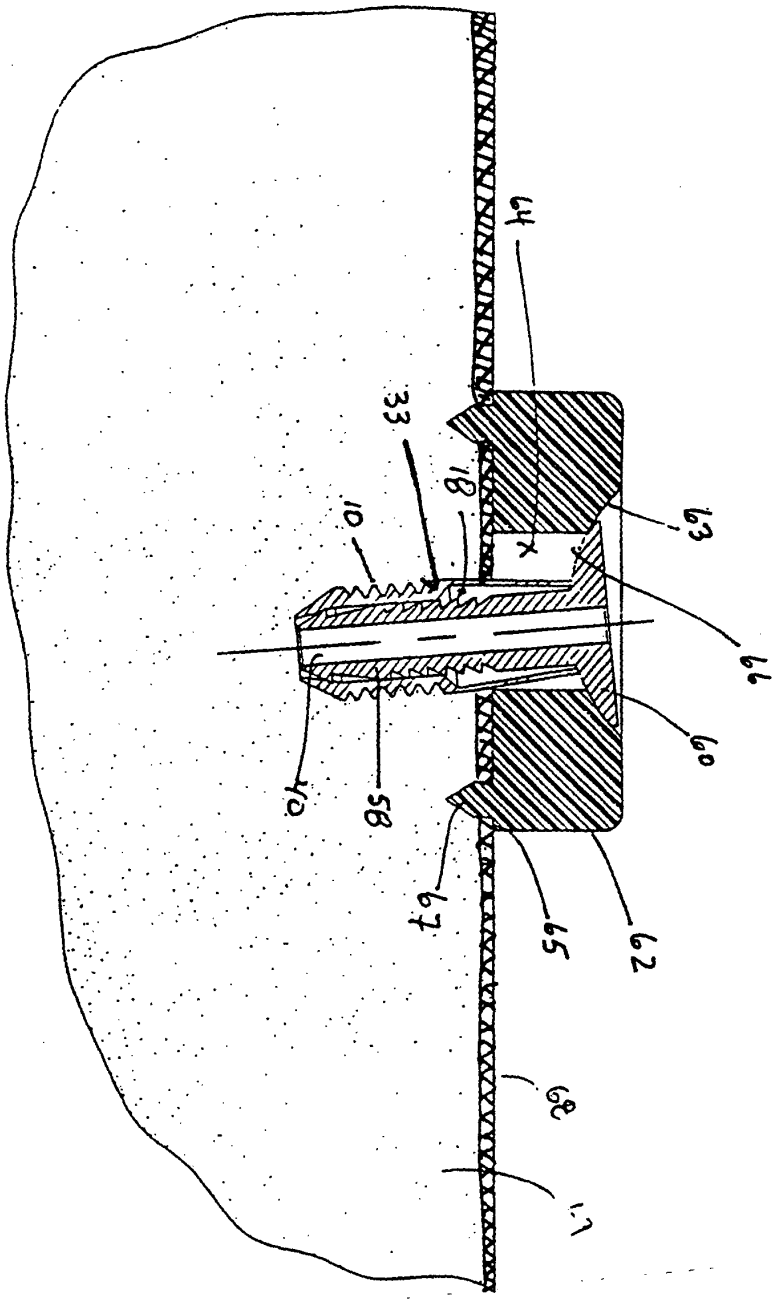


FIGURE 10

Figure 11 8/80



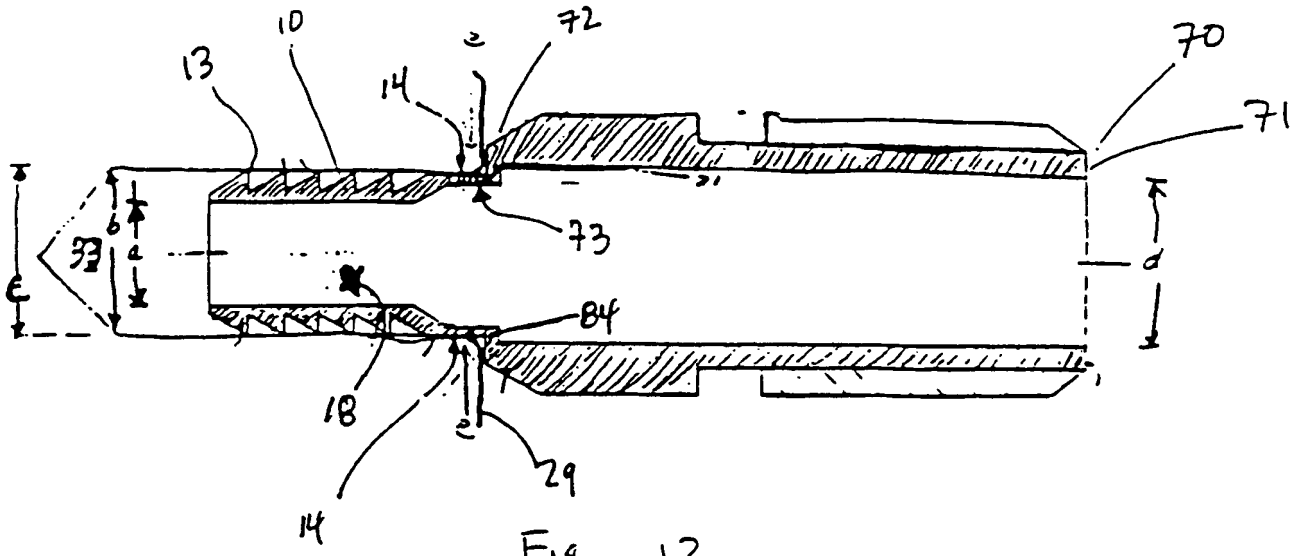
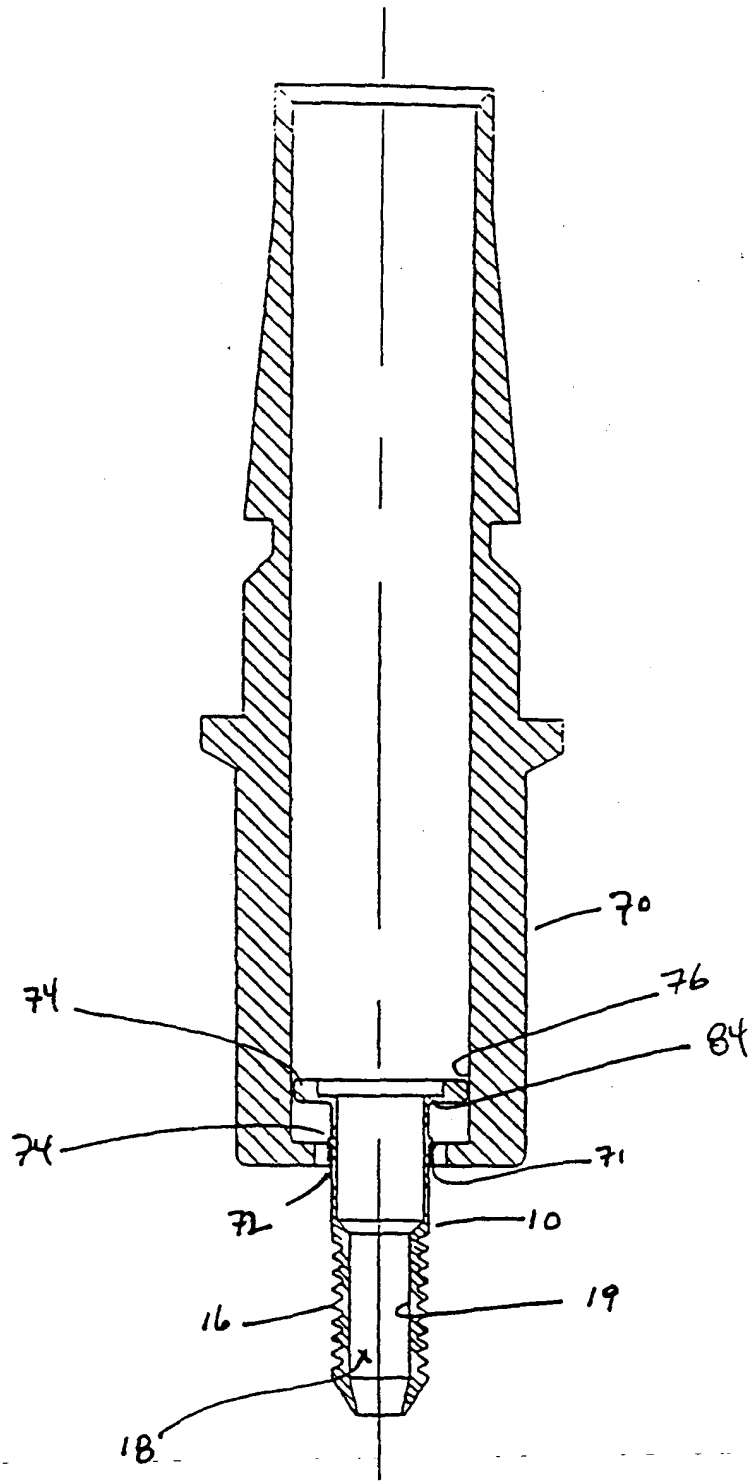
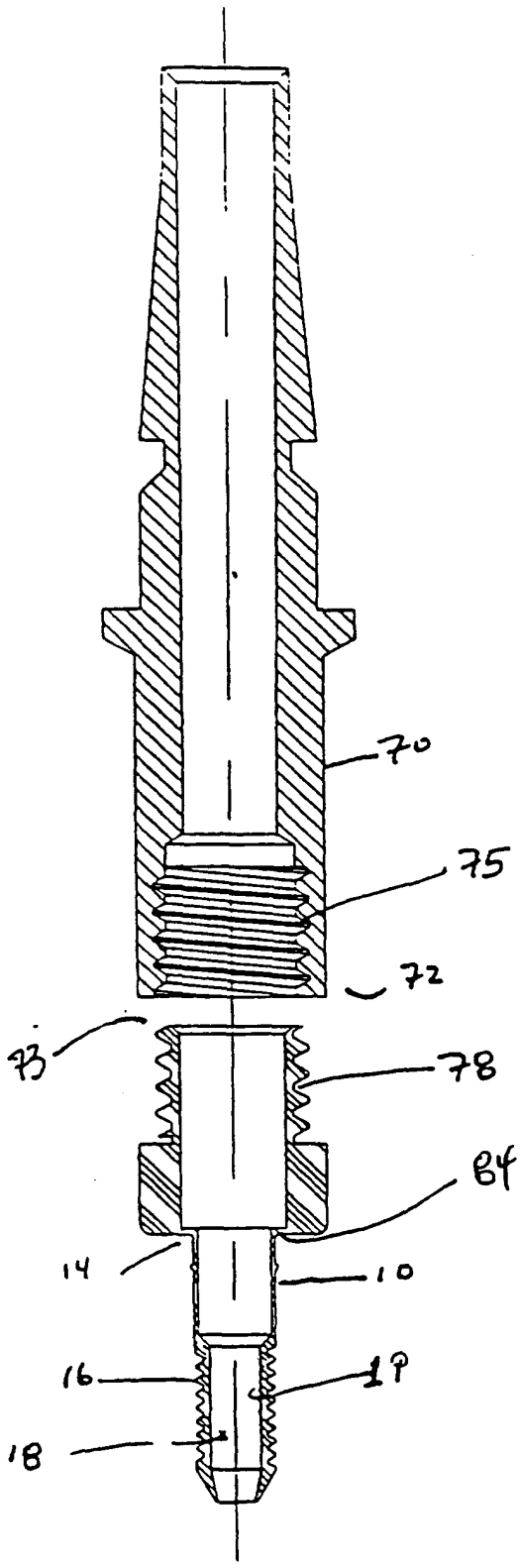


Fig 12

Figure 13



11/80 Figure 14



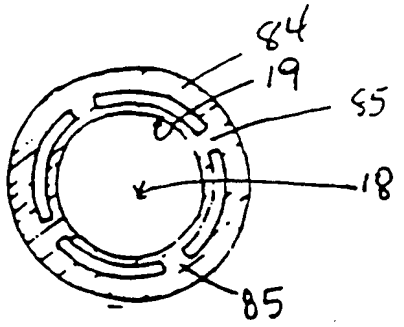


Fig 15

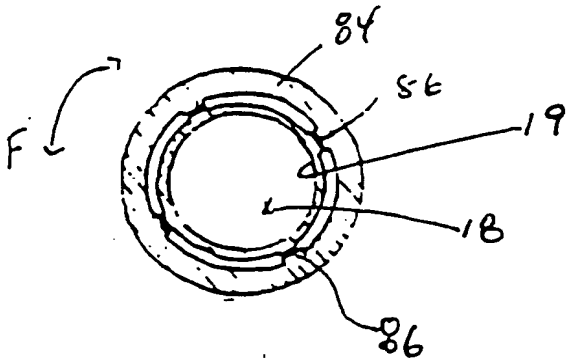


Fig 16

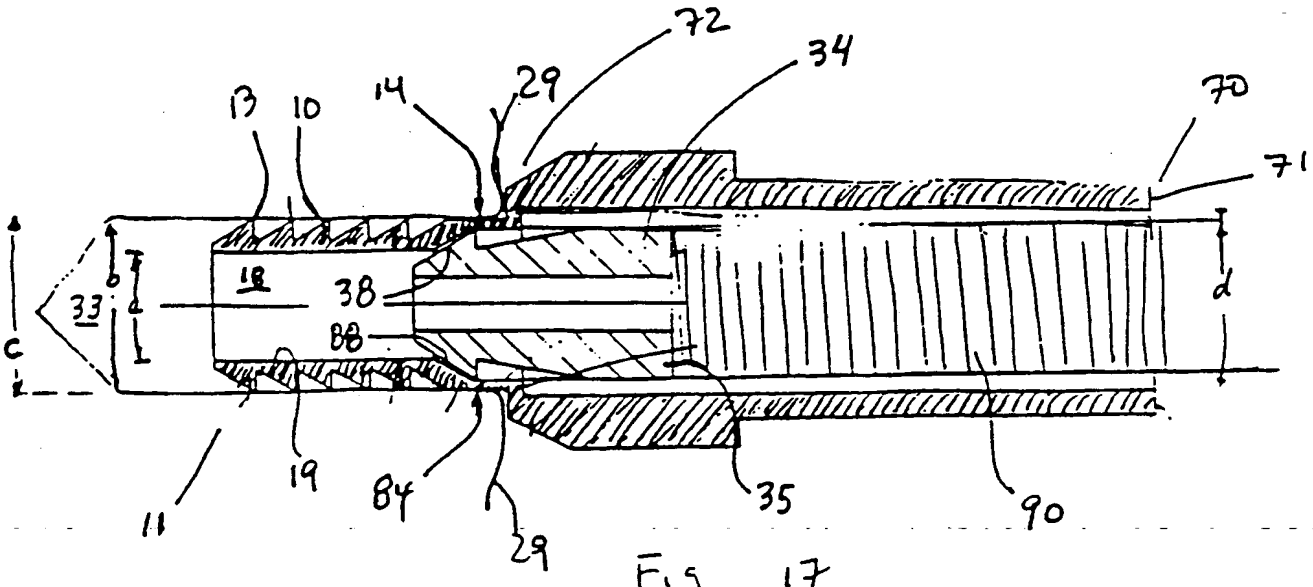


Fig. 17

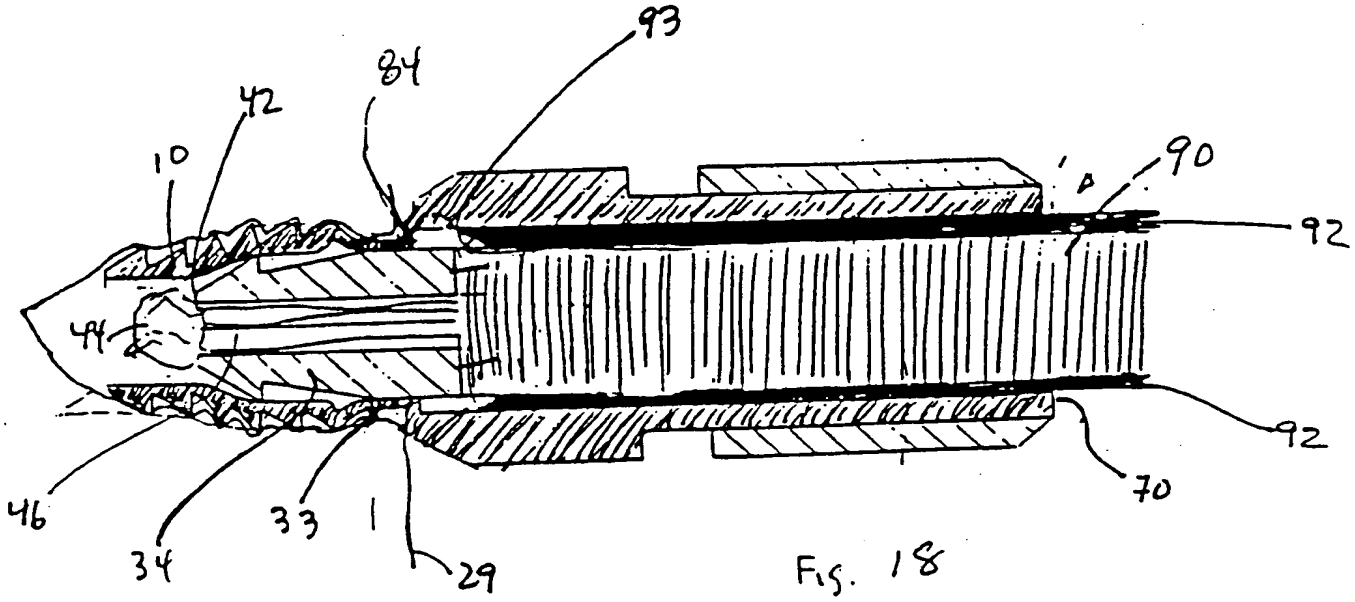


Fig. 18

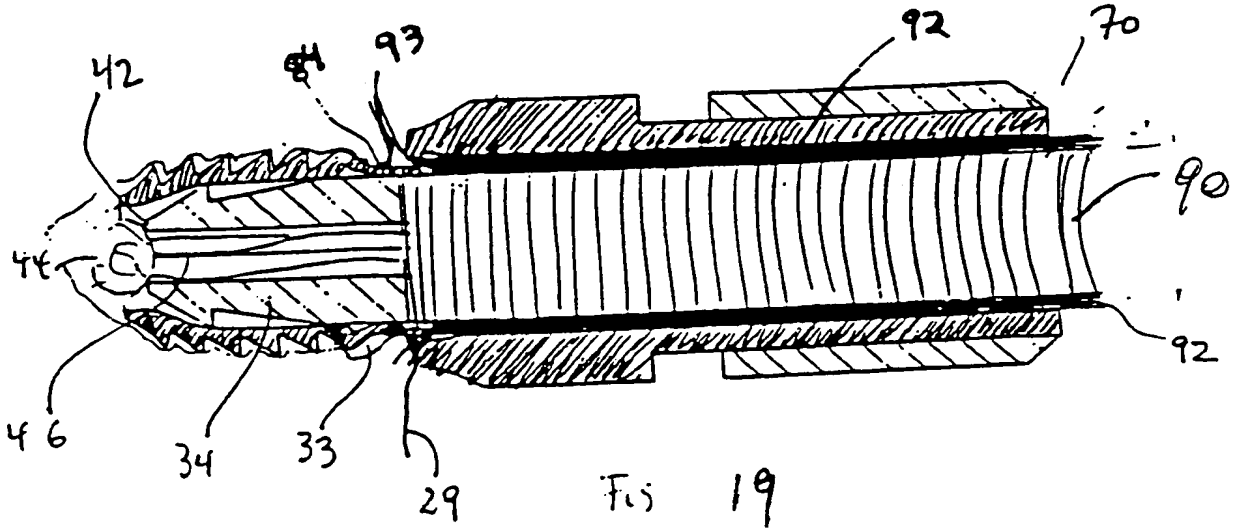


Fig 19

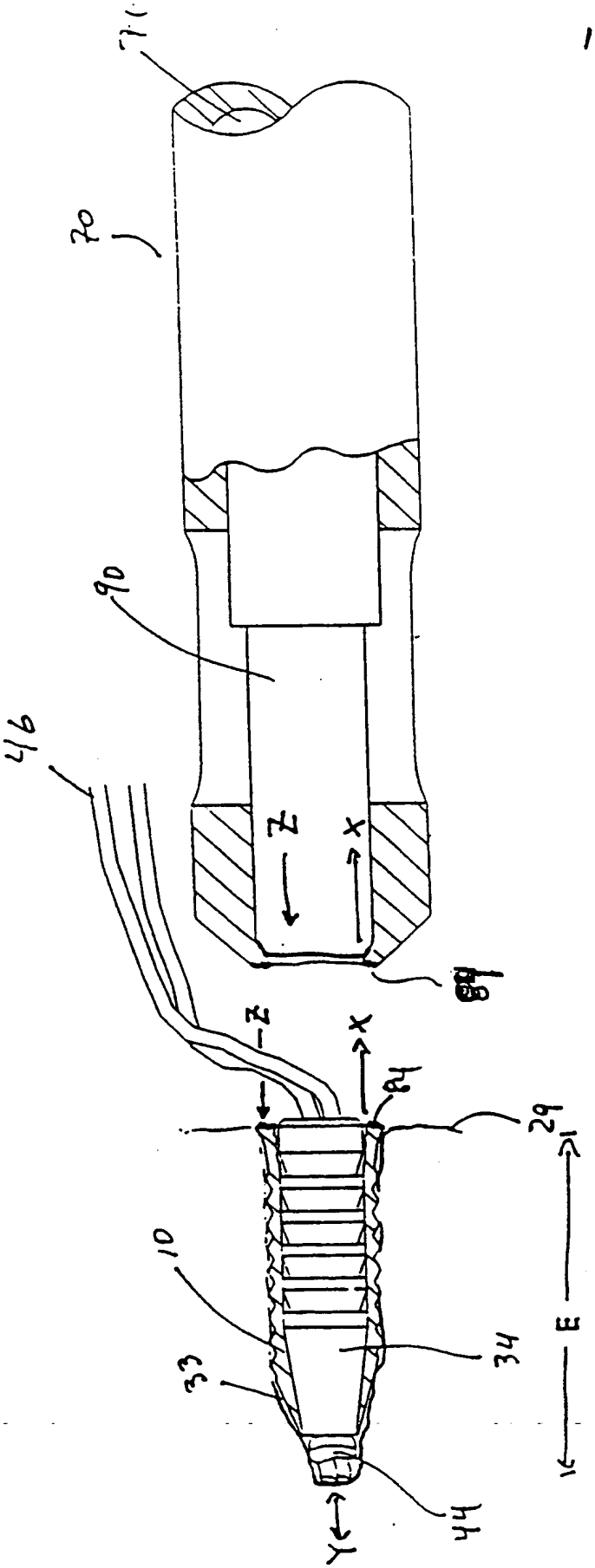


Figure 20

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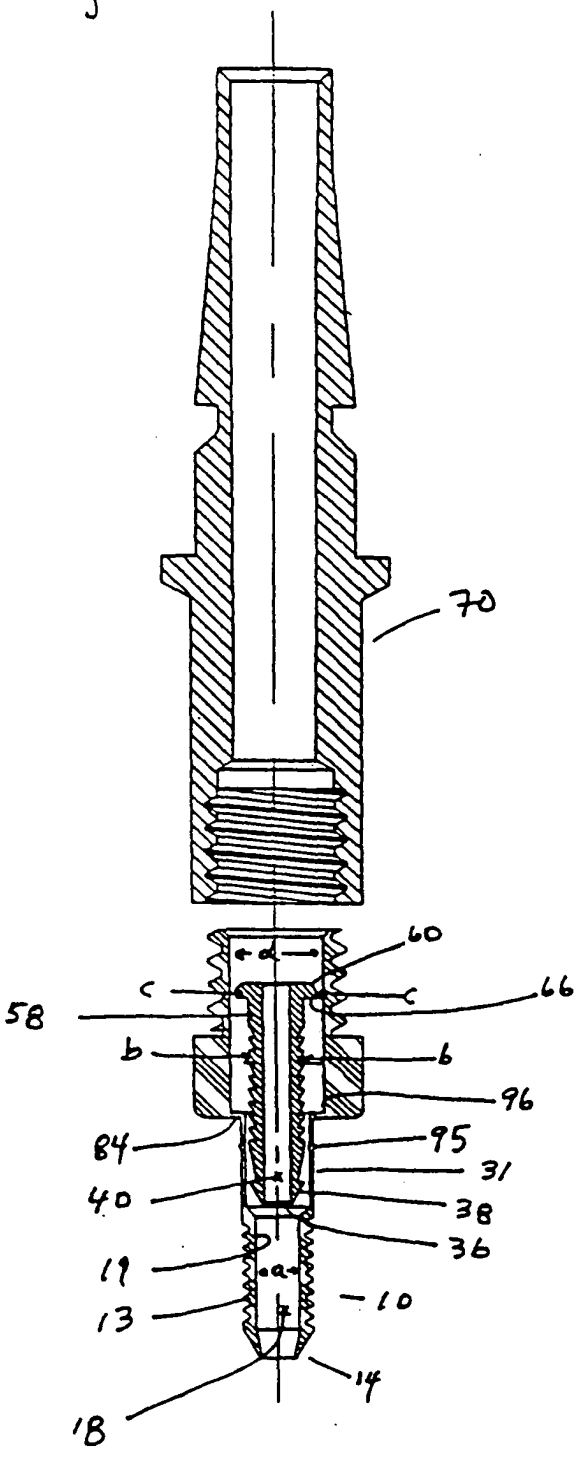
Figure 21



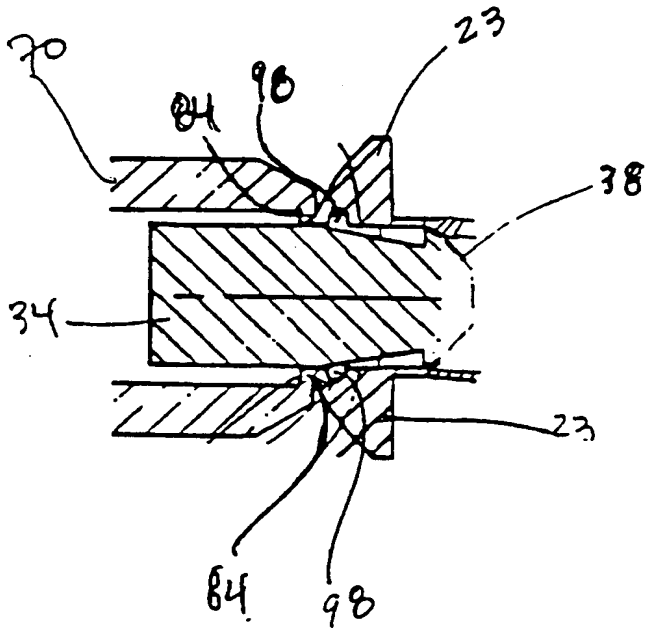


Fig. 22

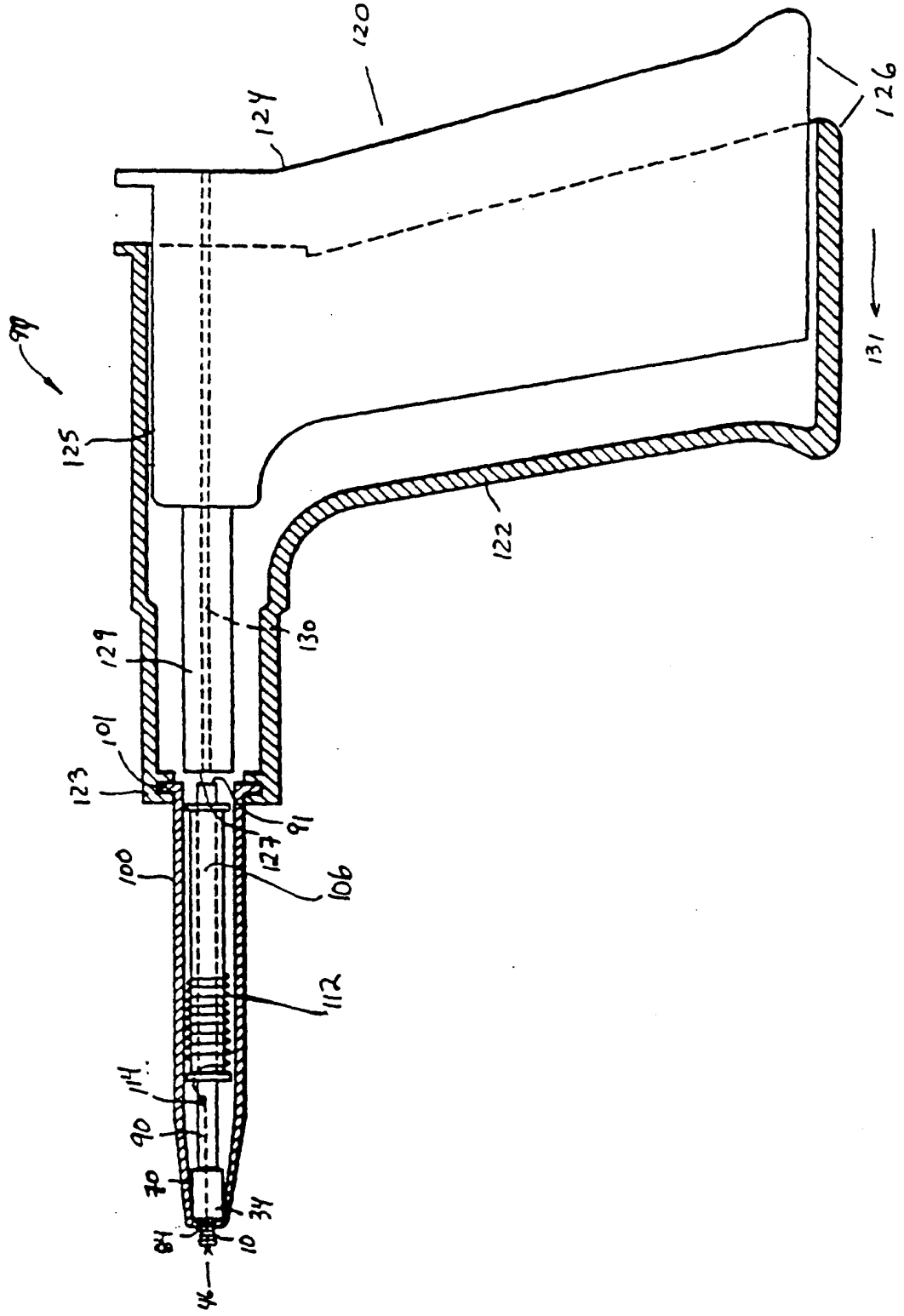


Fig. 23

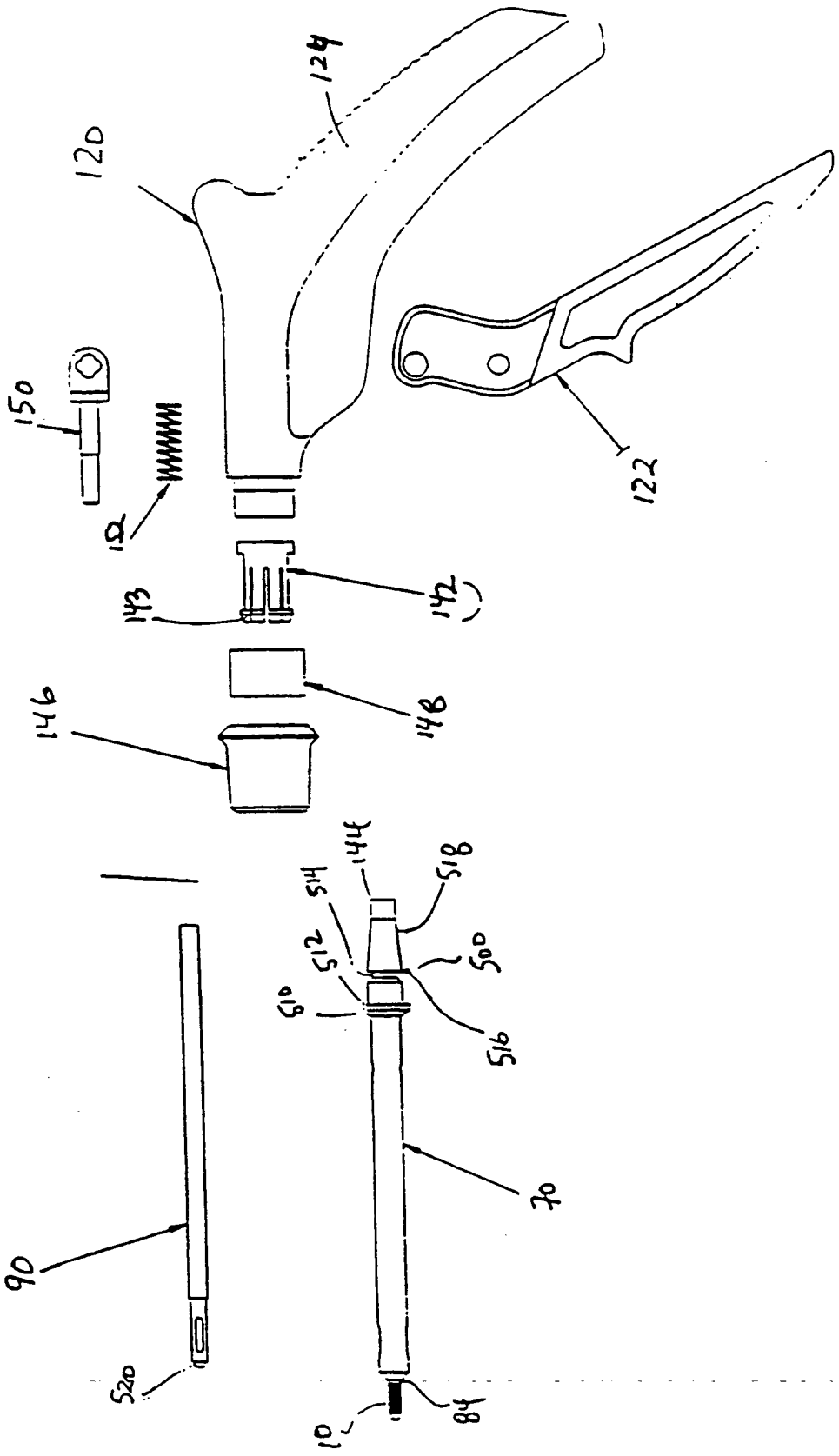
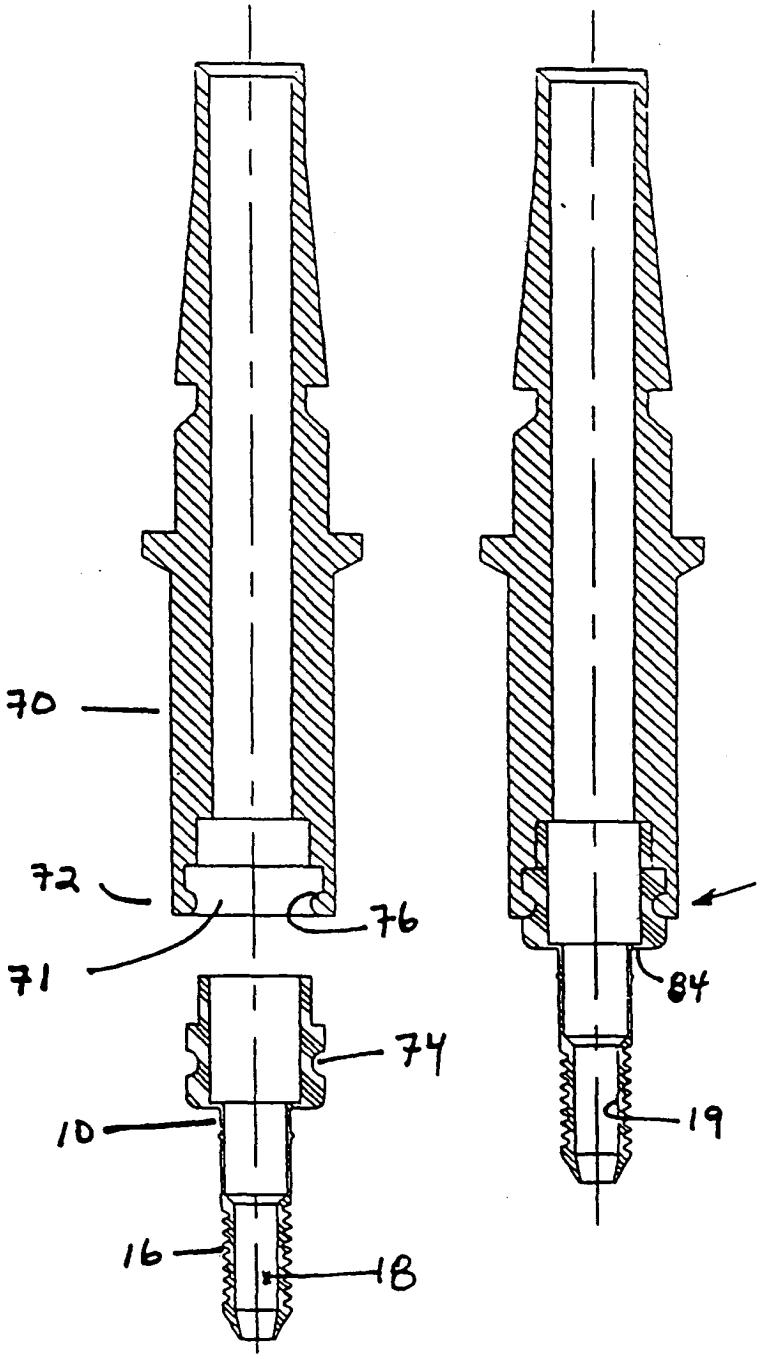


Figure 24

FIGURE 25 19/80



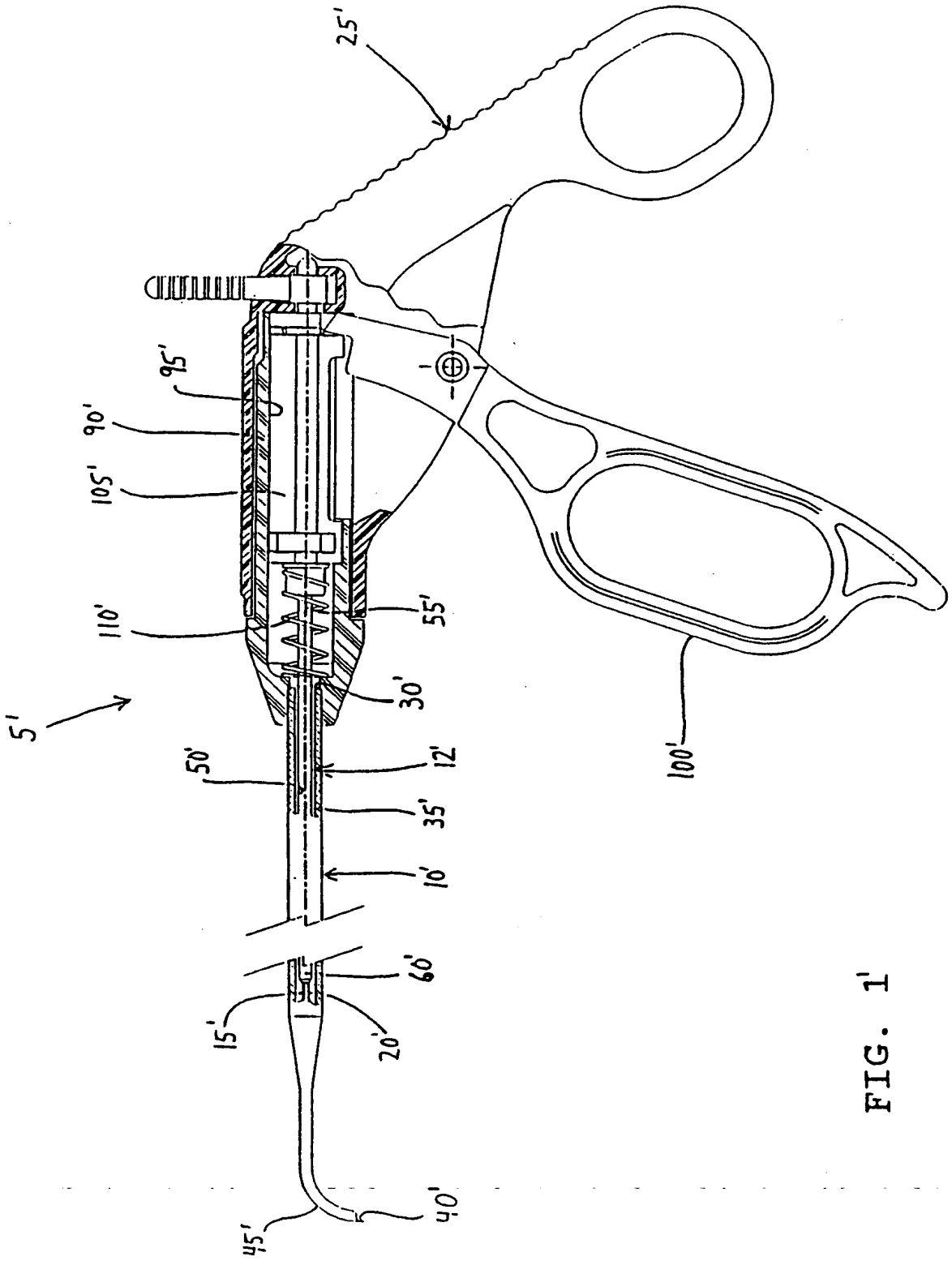


FIG. 1'

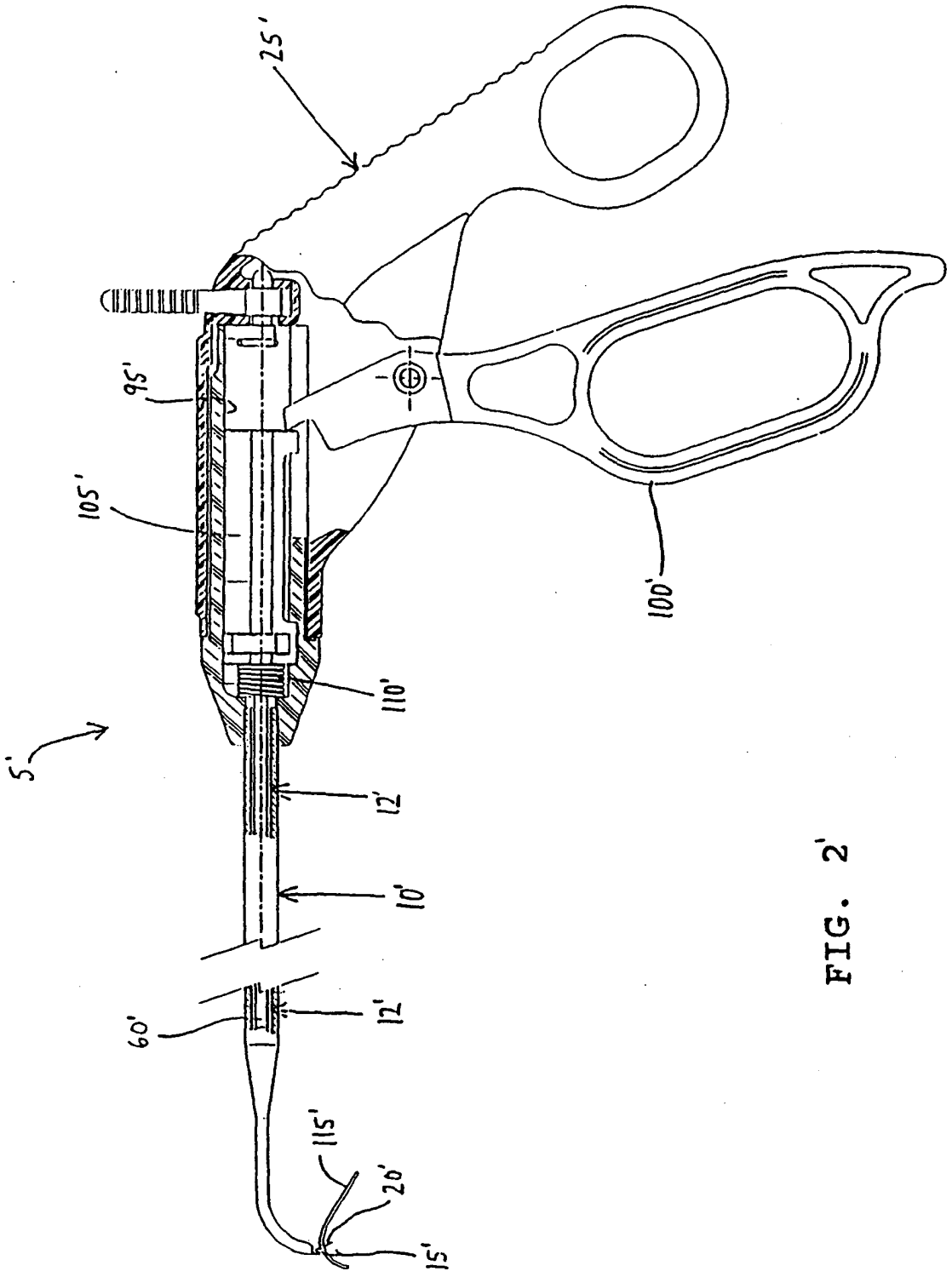


FIG. 2'

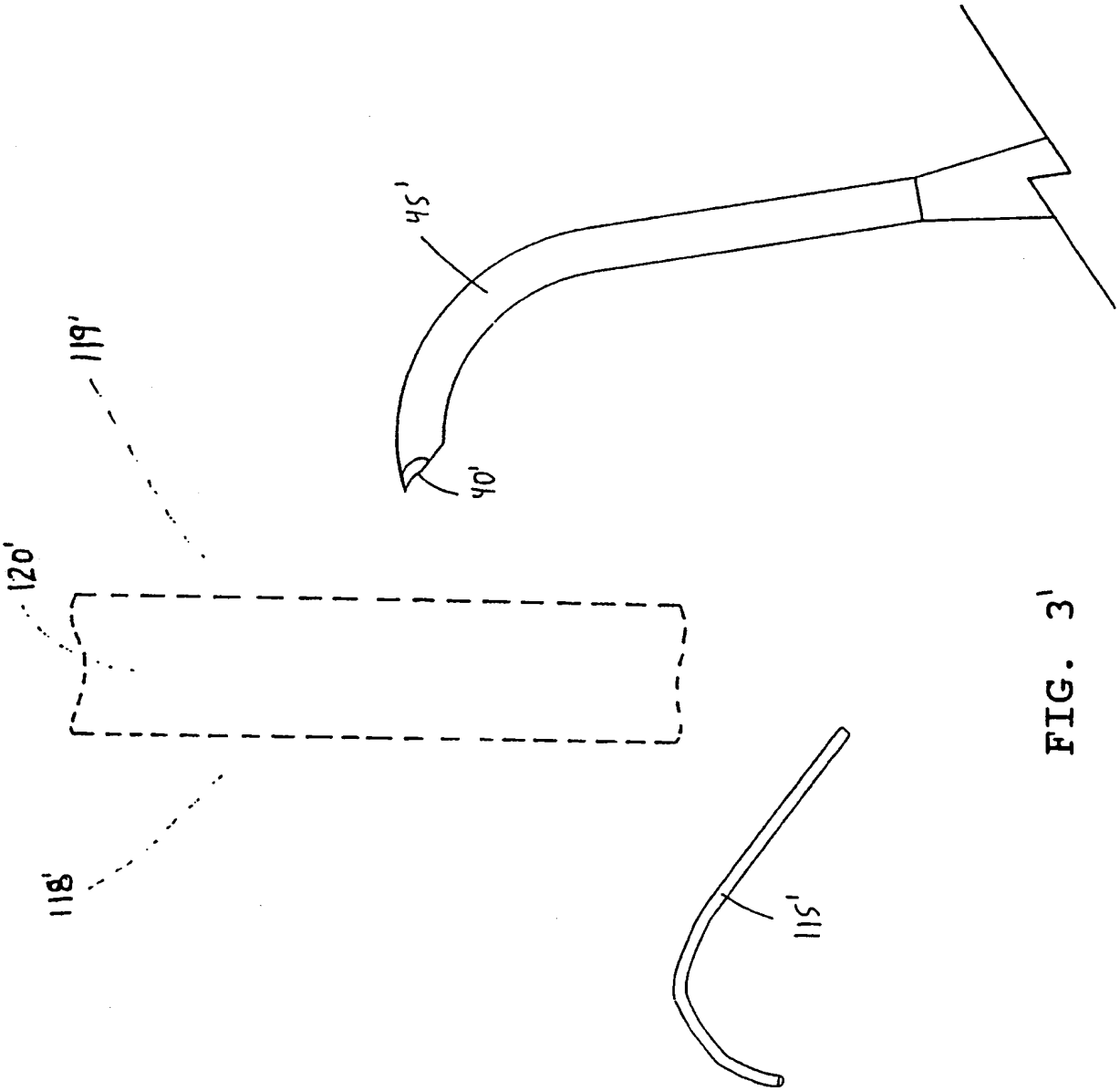


FIG. 3'

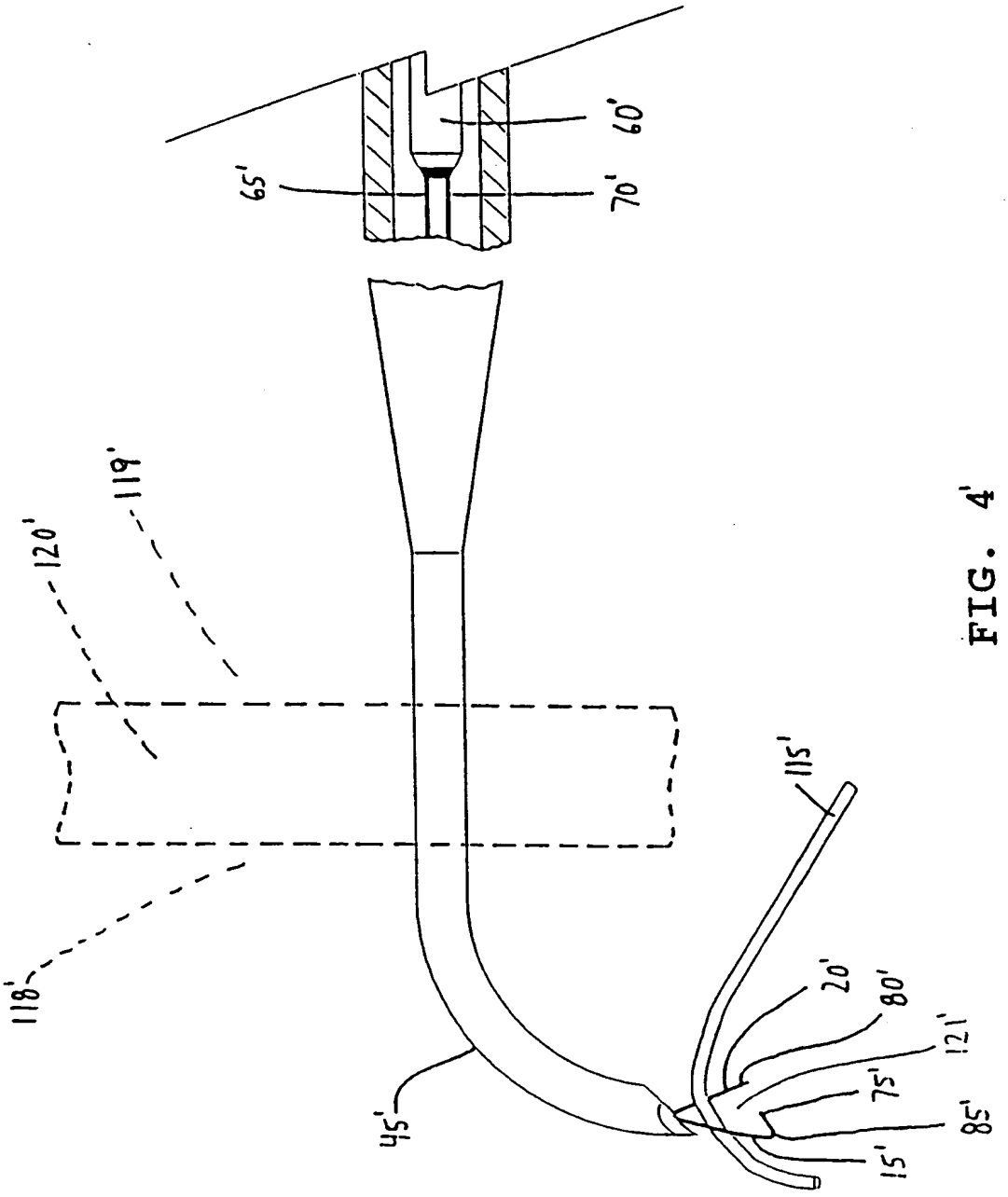


FIG. 4'

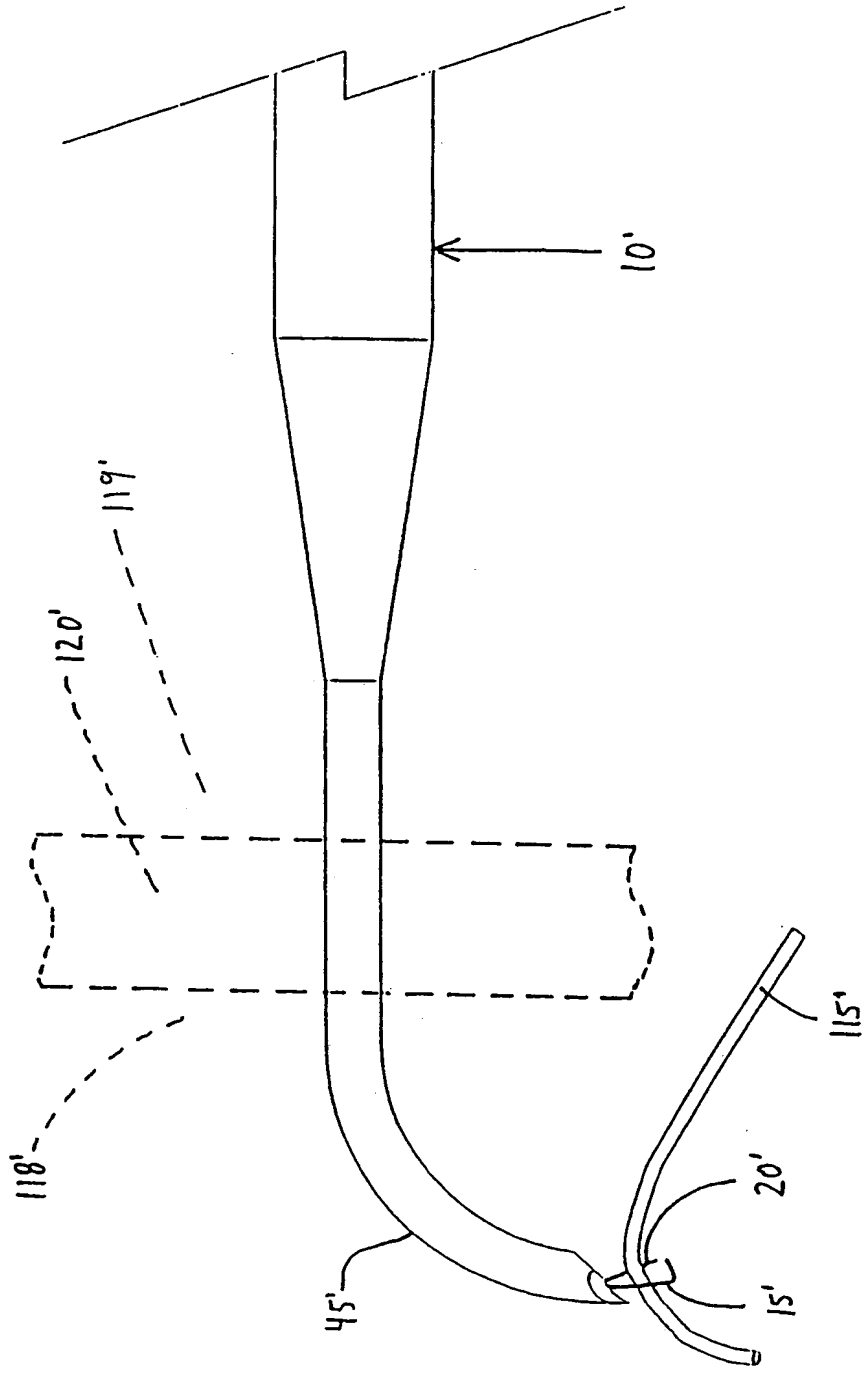


FIG. 5'

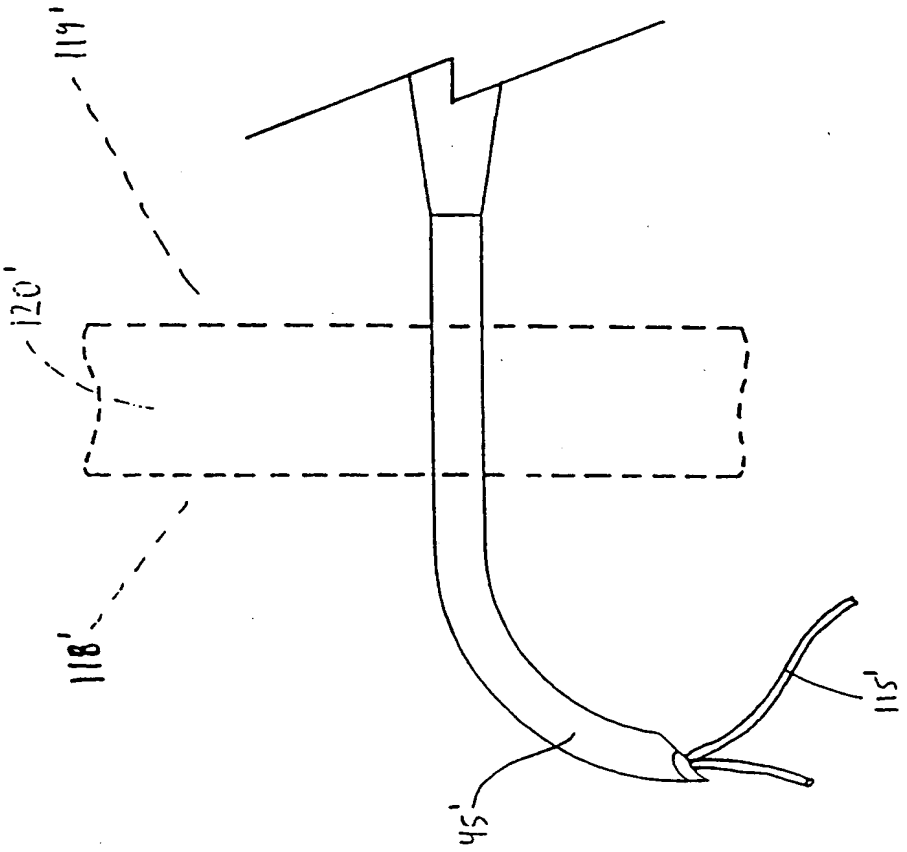


FIG. 6'

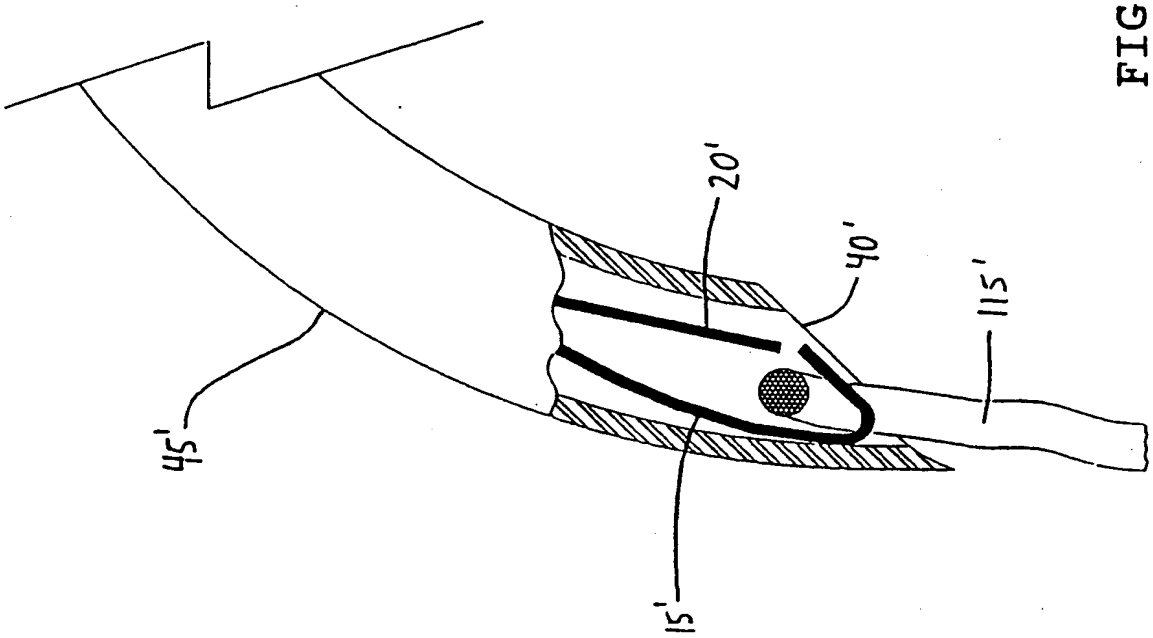


FIG. 7'

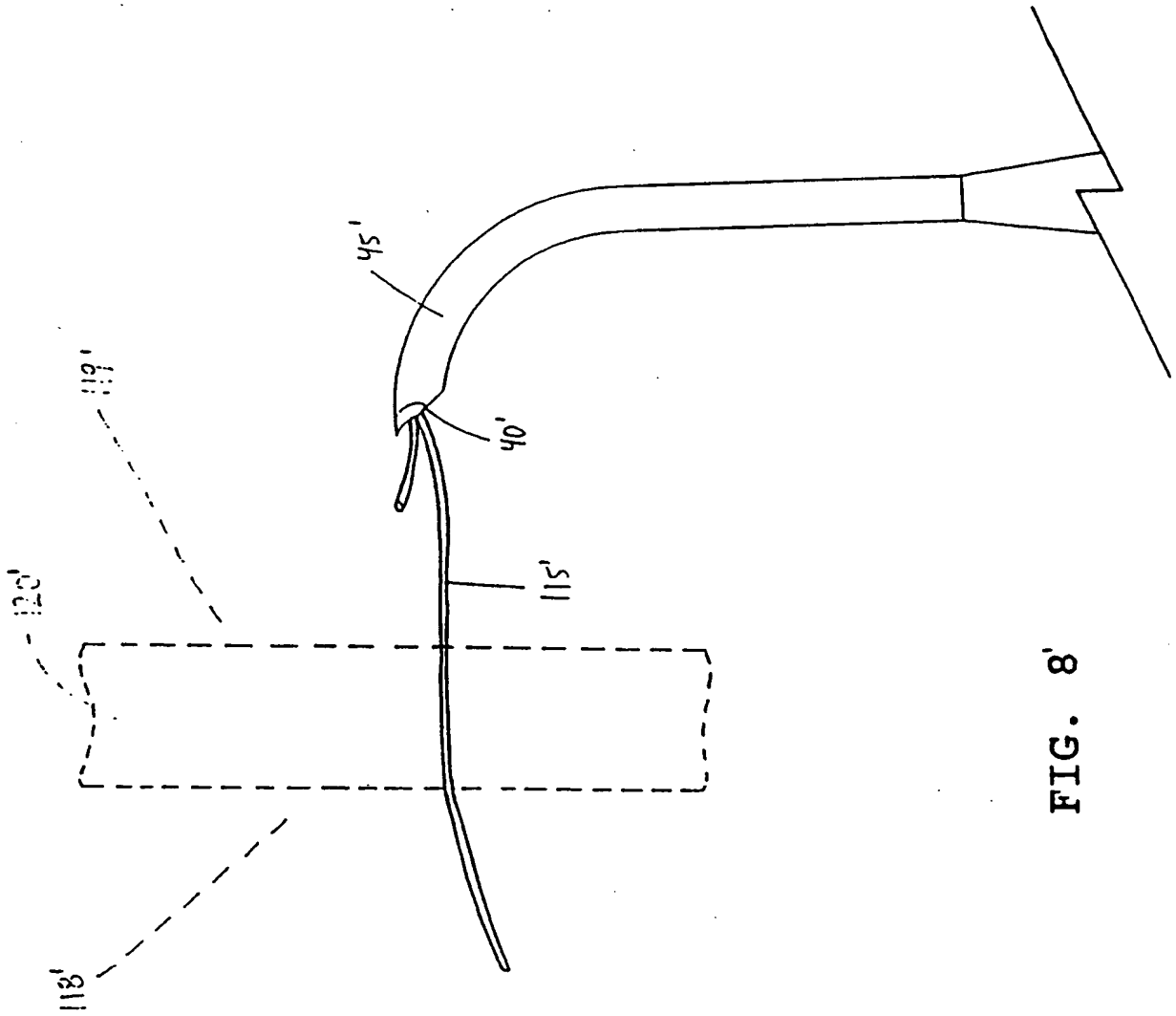


FIG. 8'

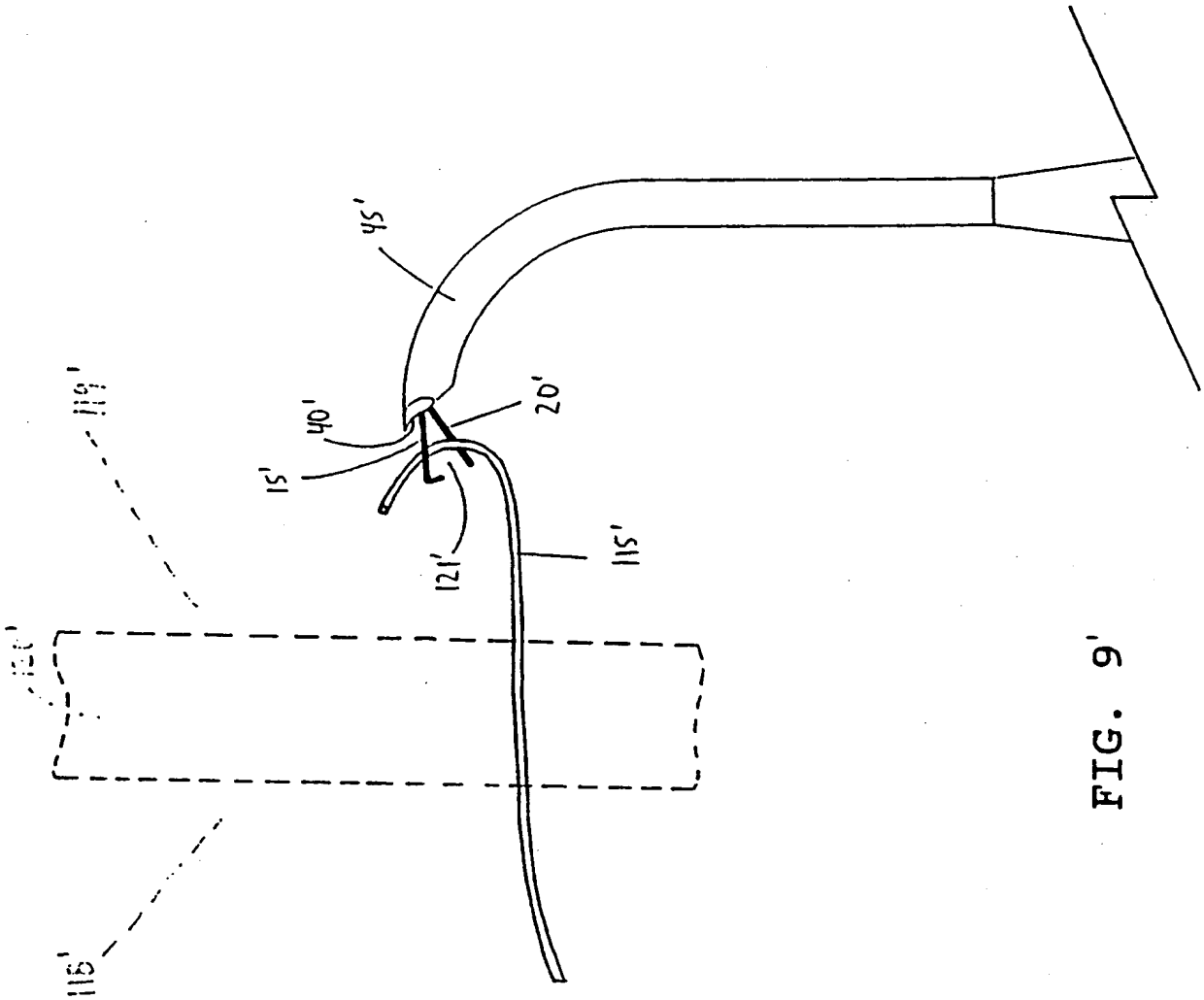


FIG. 9'

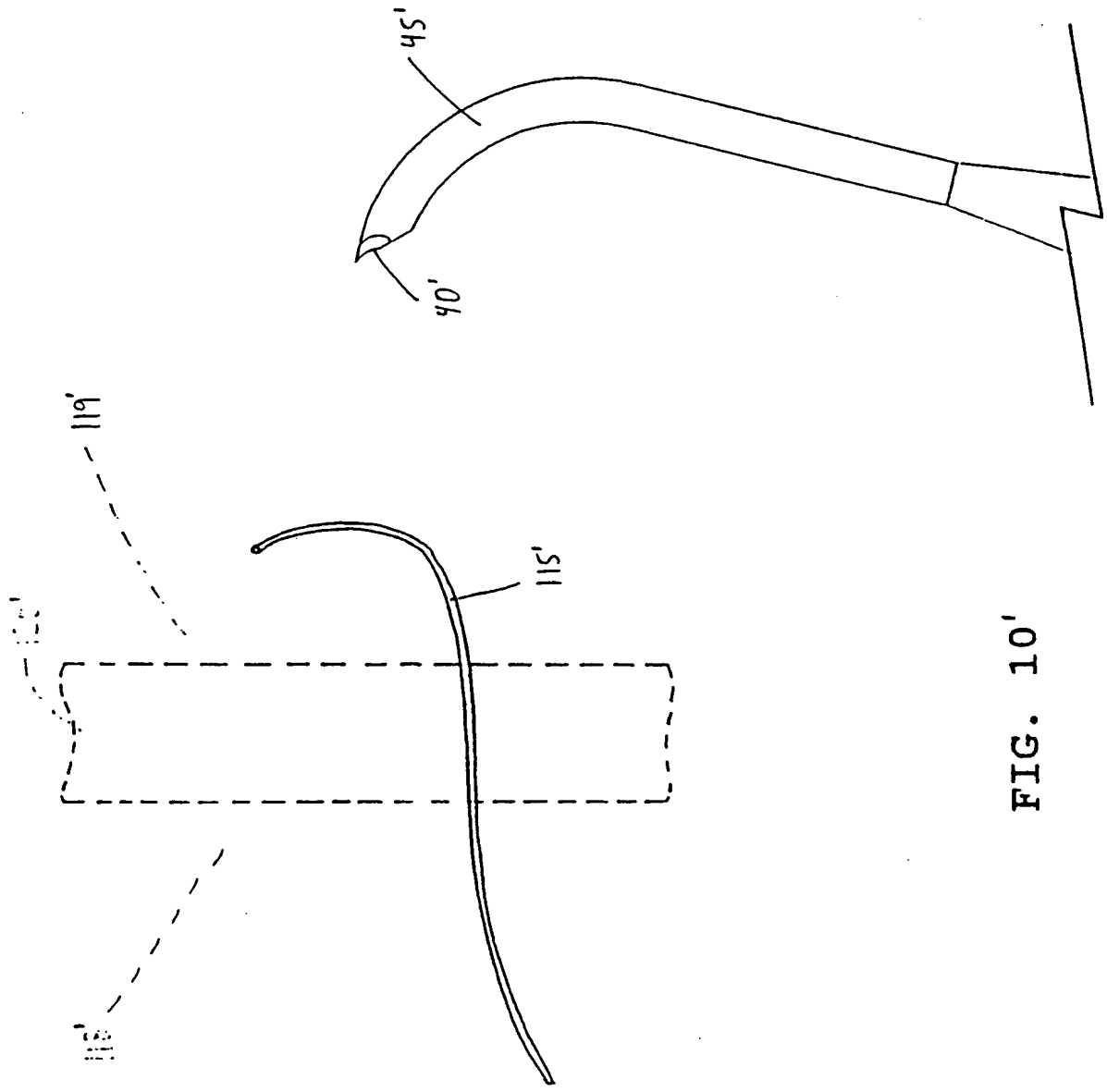


FIG. 10'

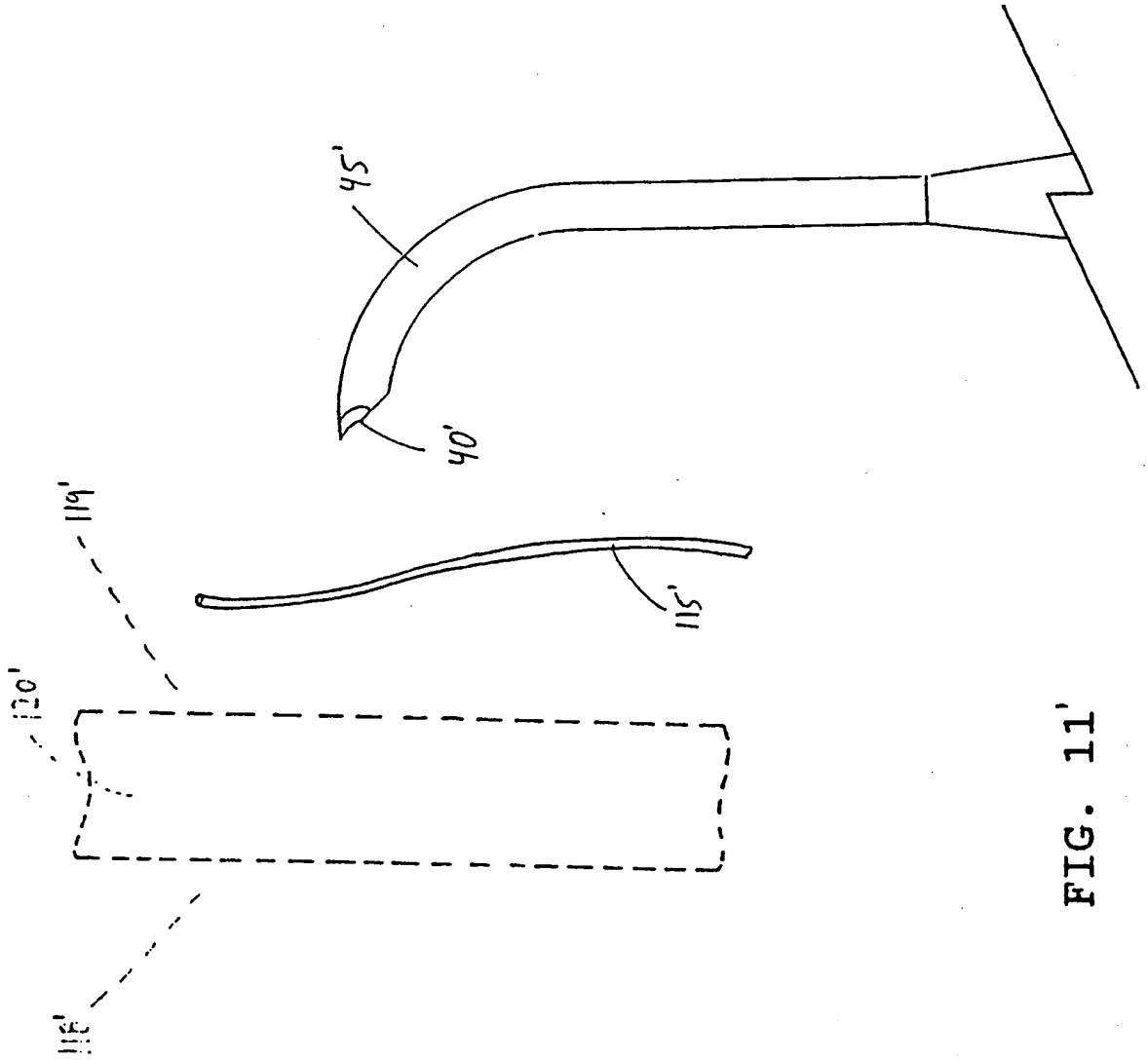


FIG. 11'

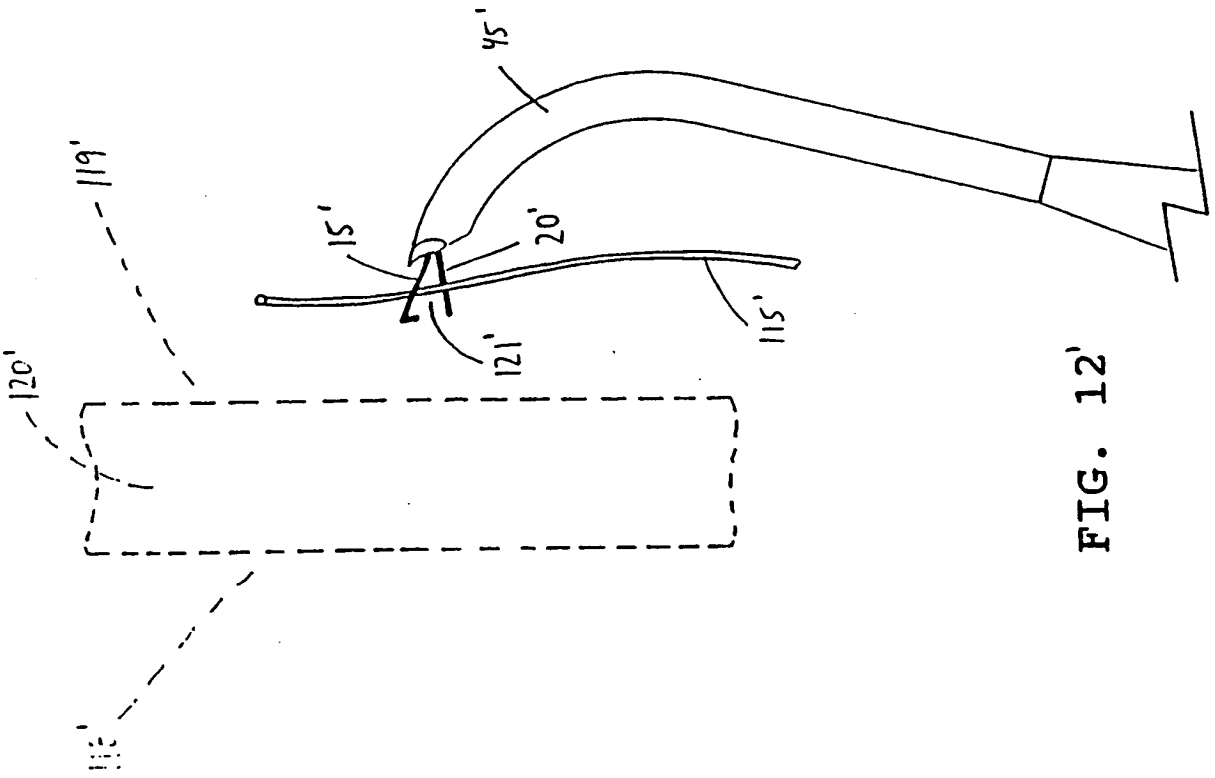


FIG. 12'

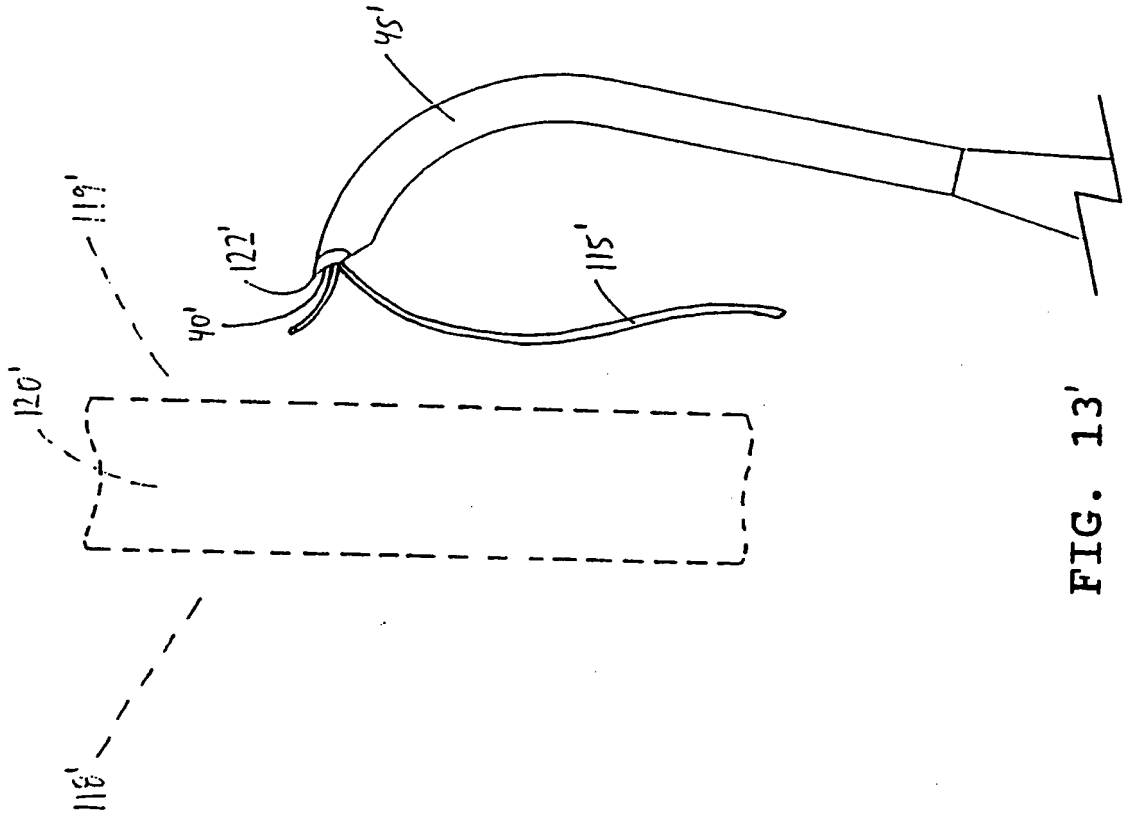


FIG. 13'

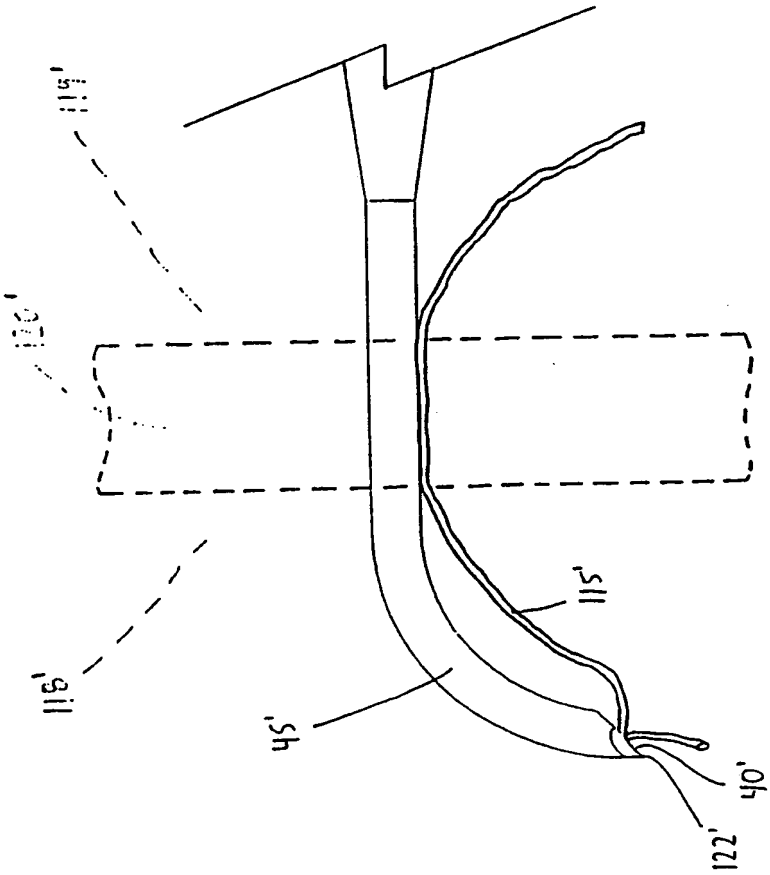


FIG. 14'

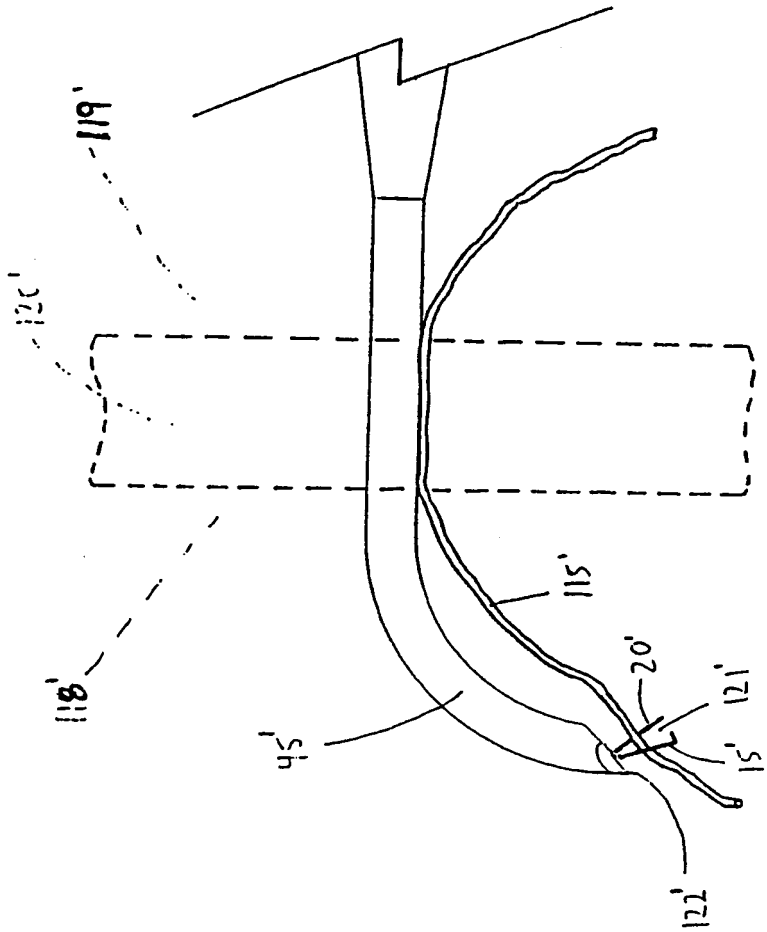


FIG. 15'

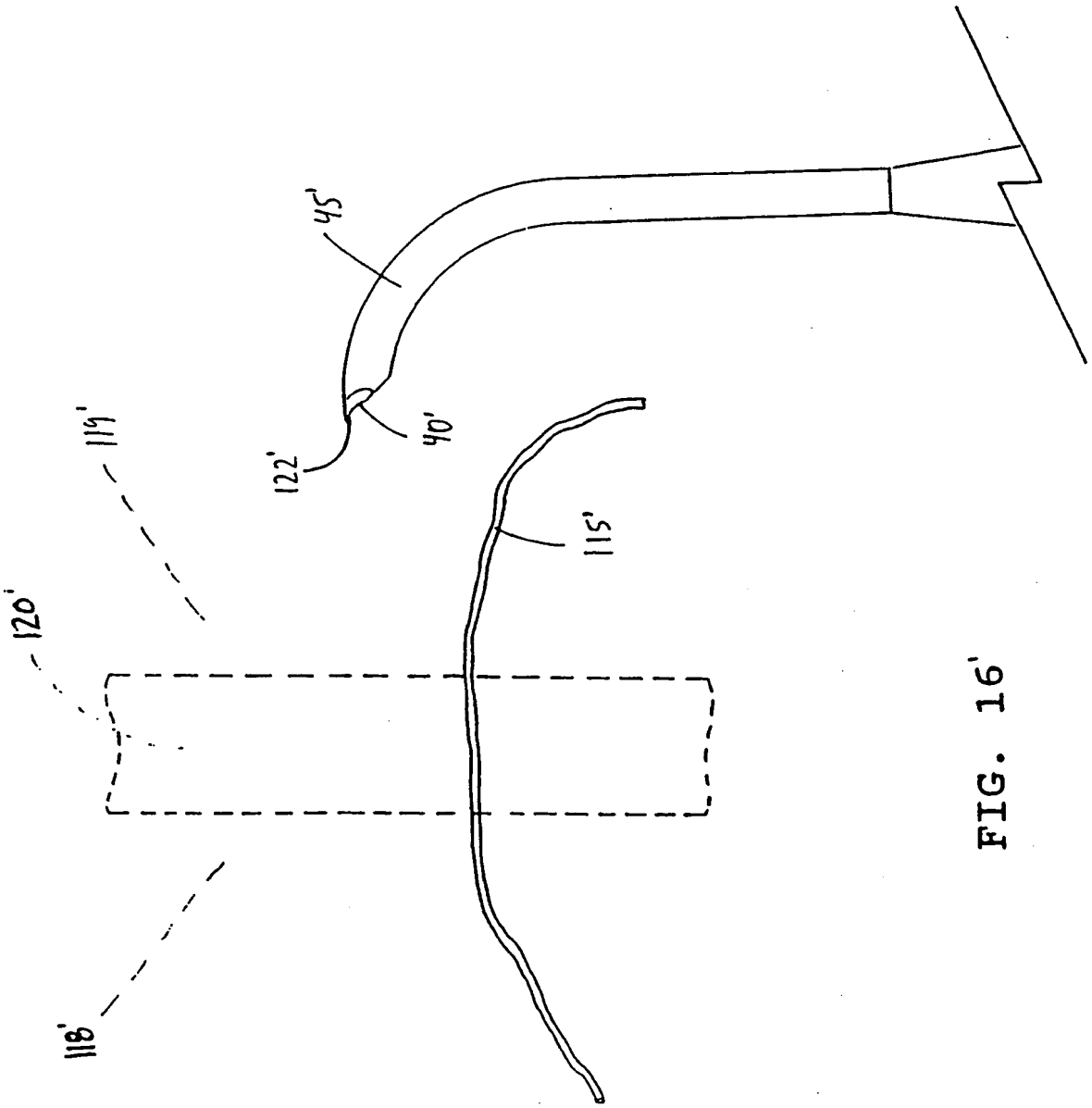


FIG. 16'

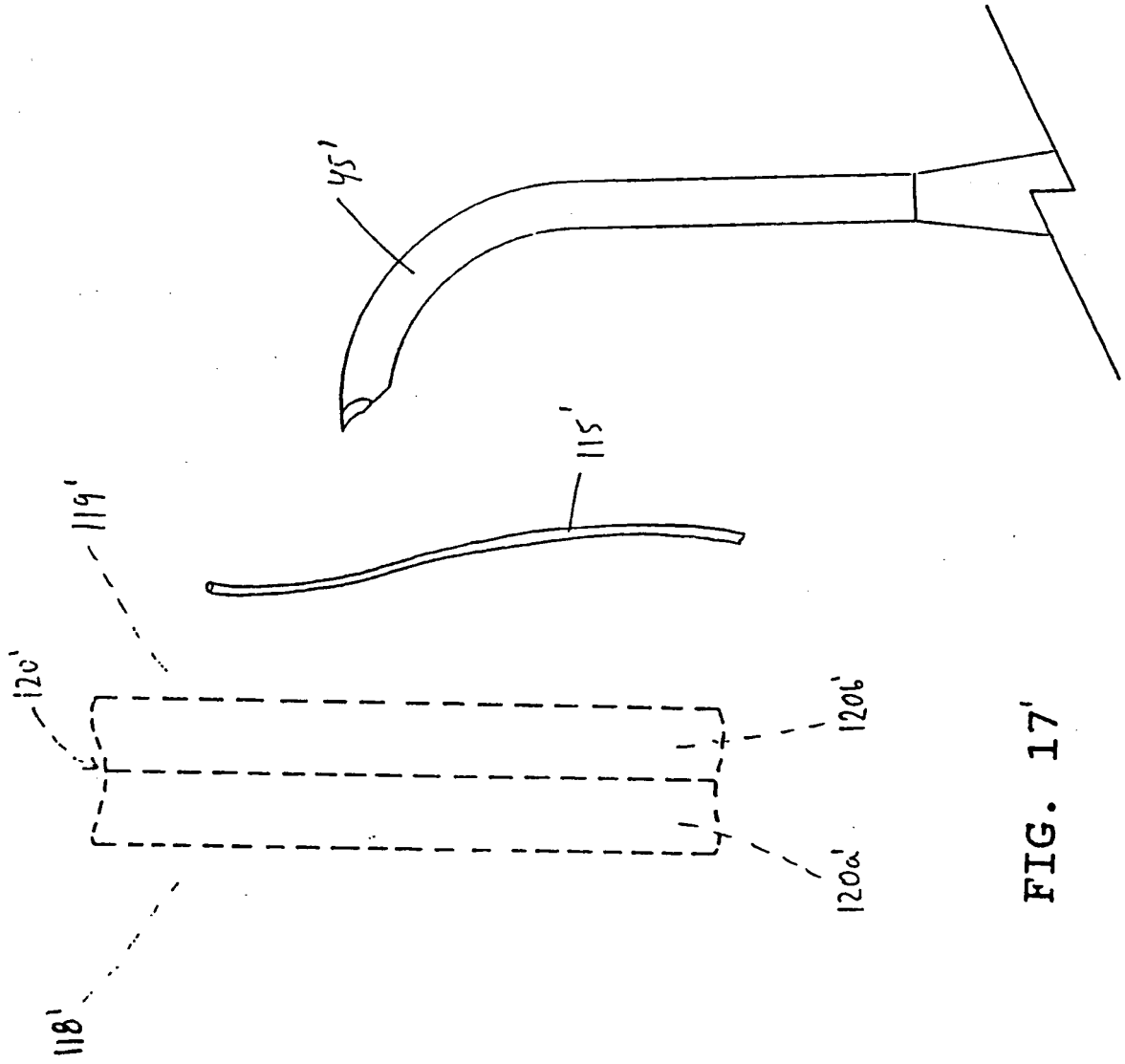


FIG. 17'

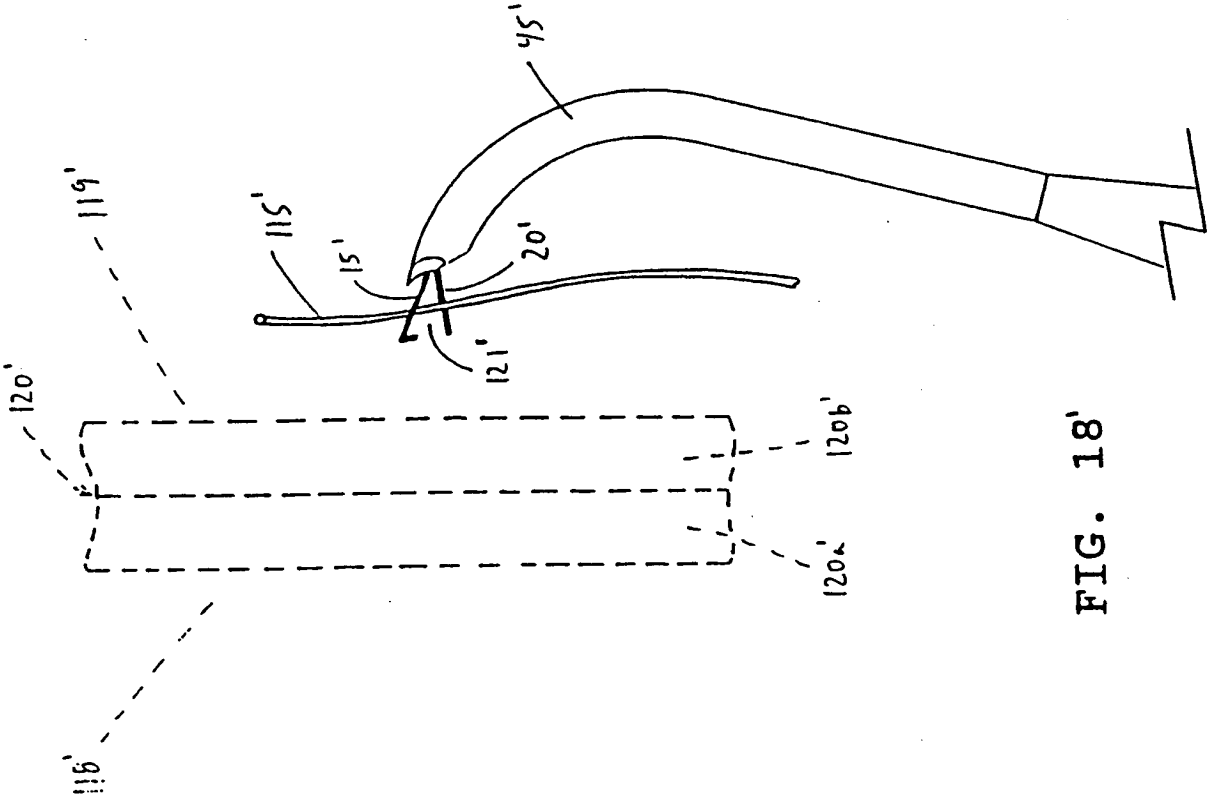


FIG. 18'

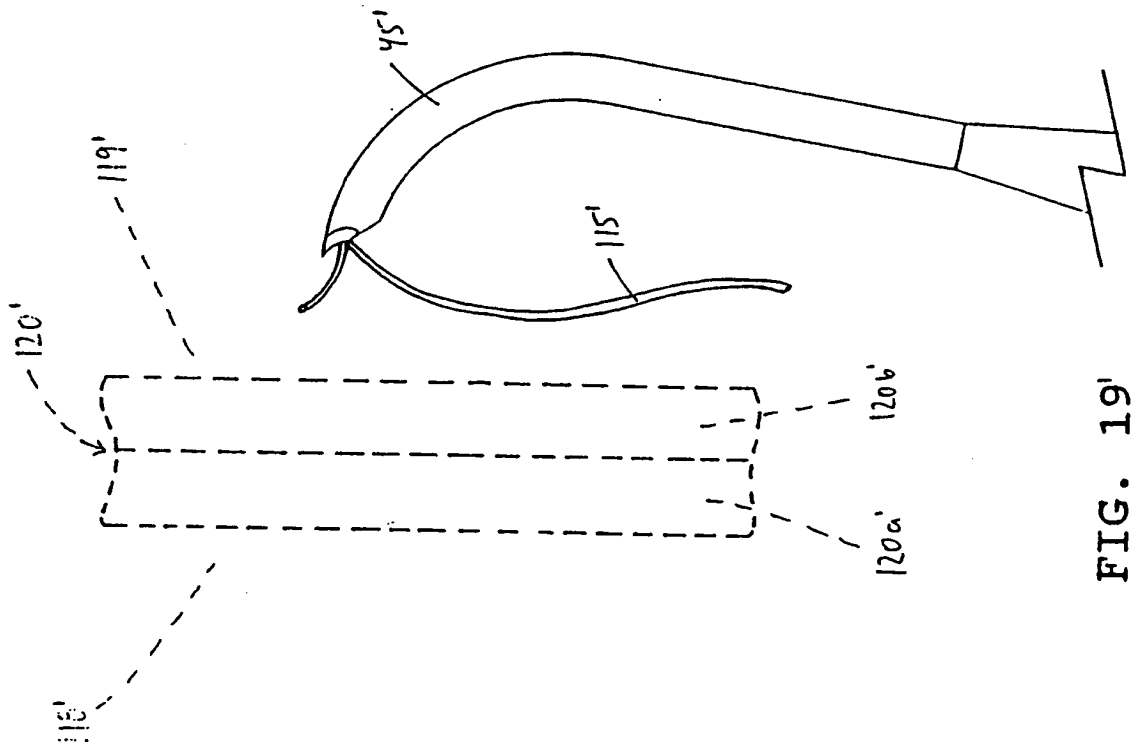


FIG. 19'

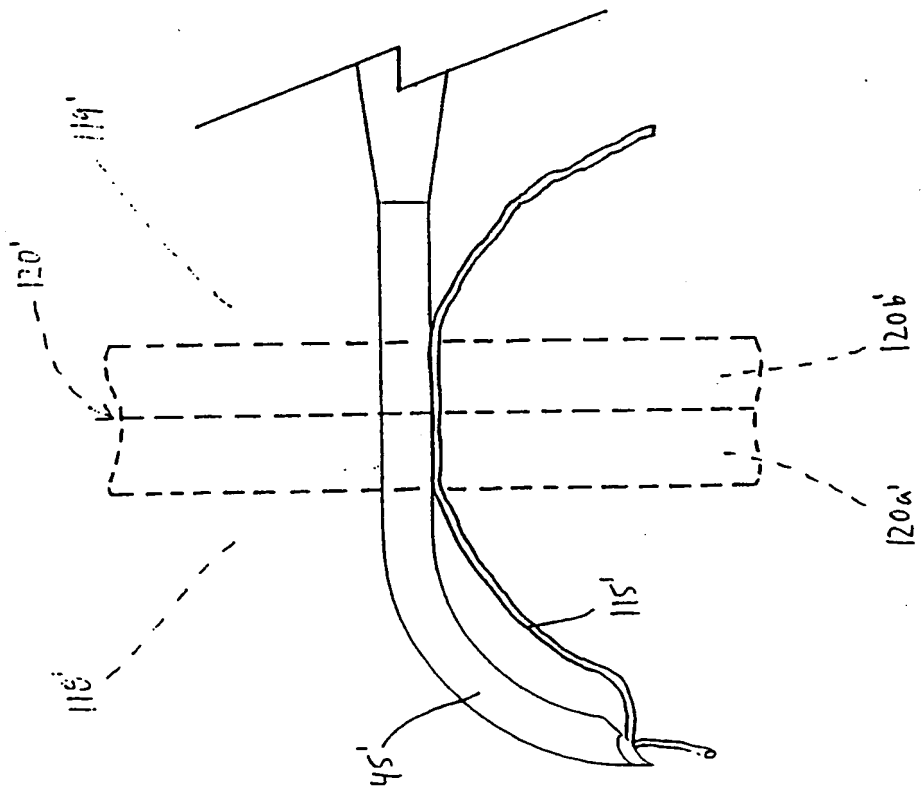


FIG. 20'

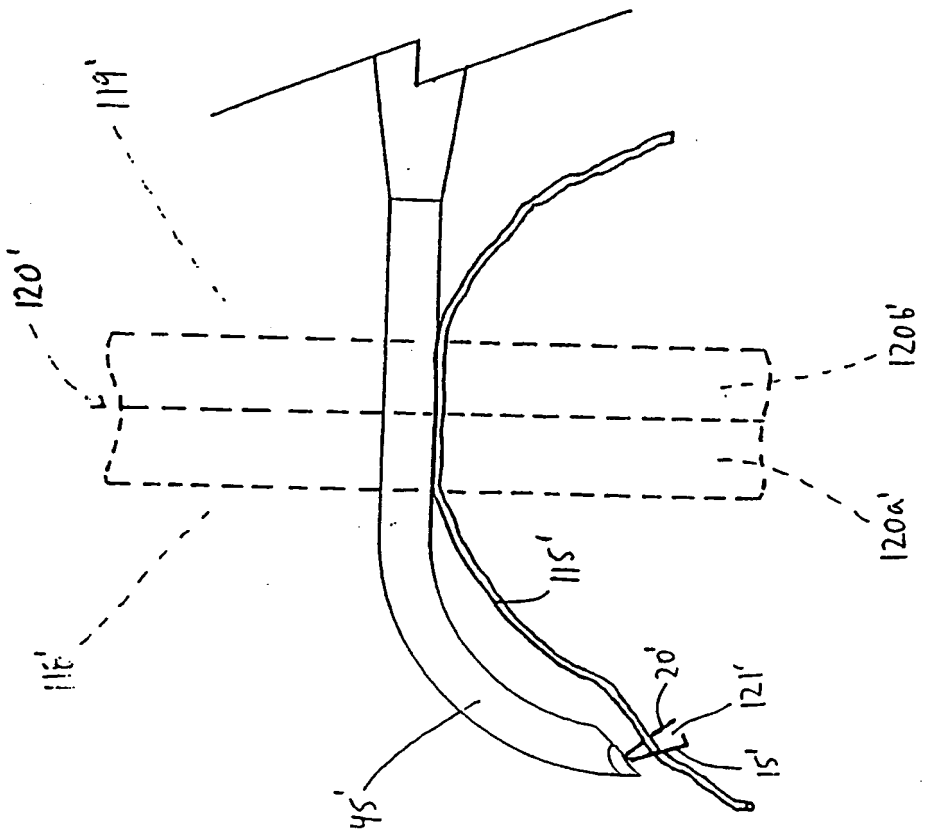


FIG. 21'

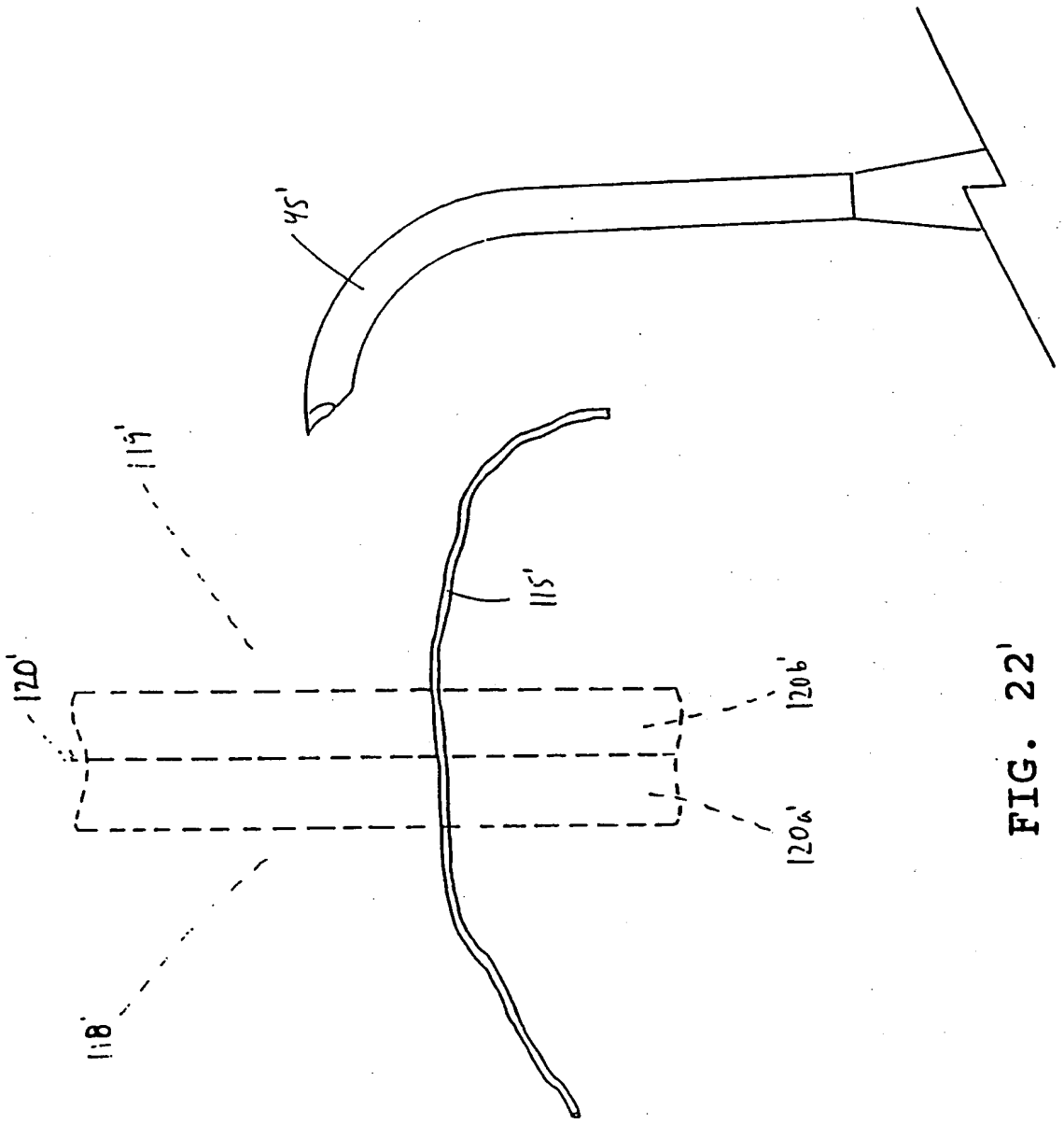


FIG. 22'

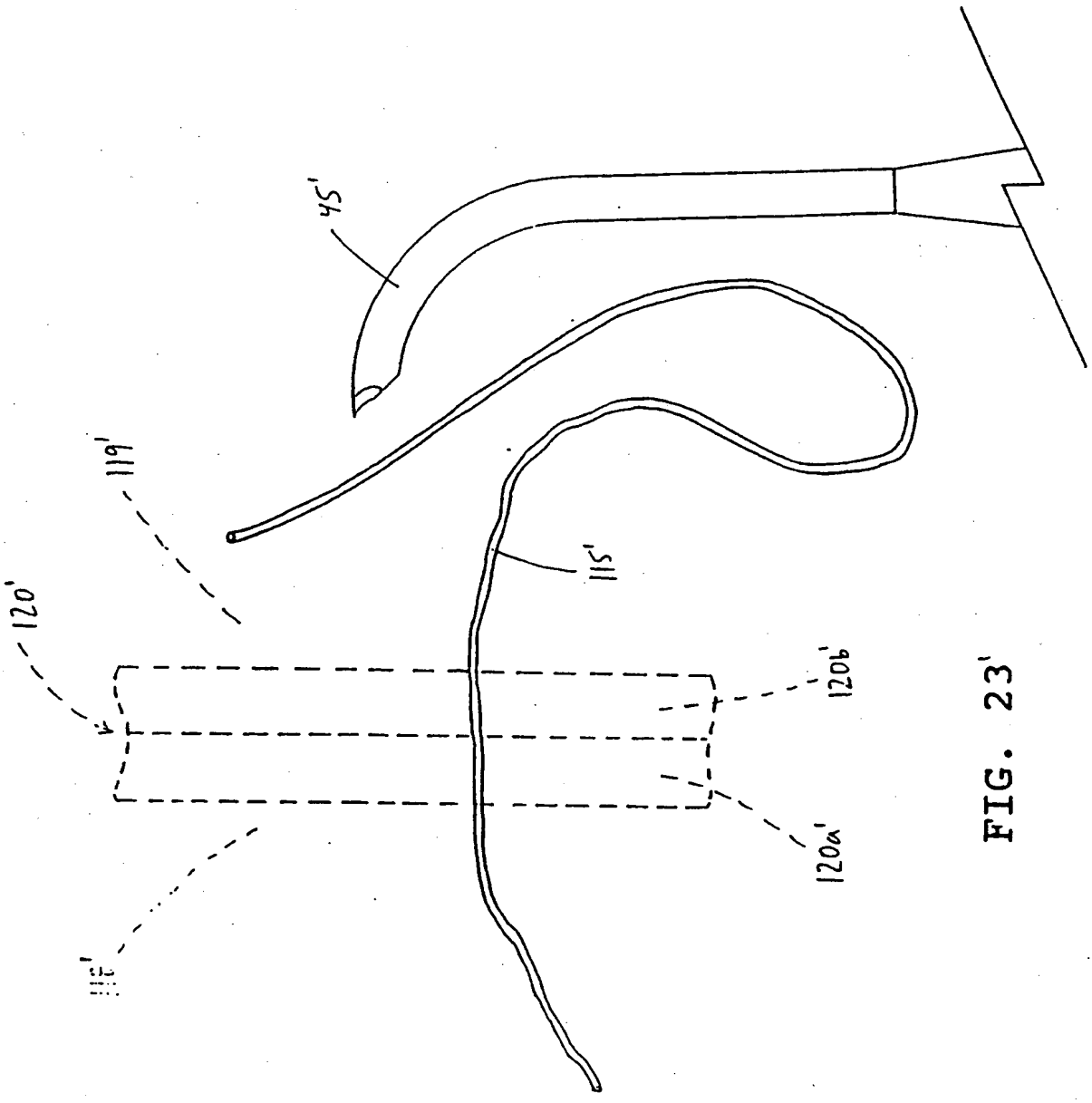


FIG. 23'

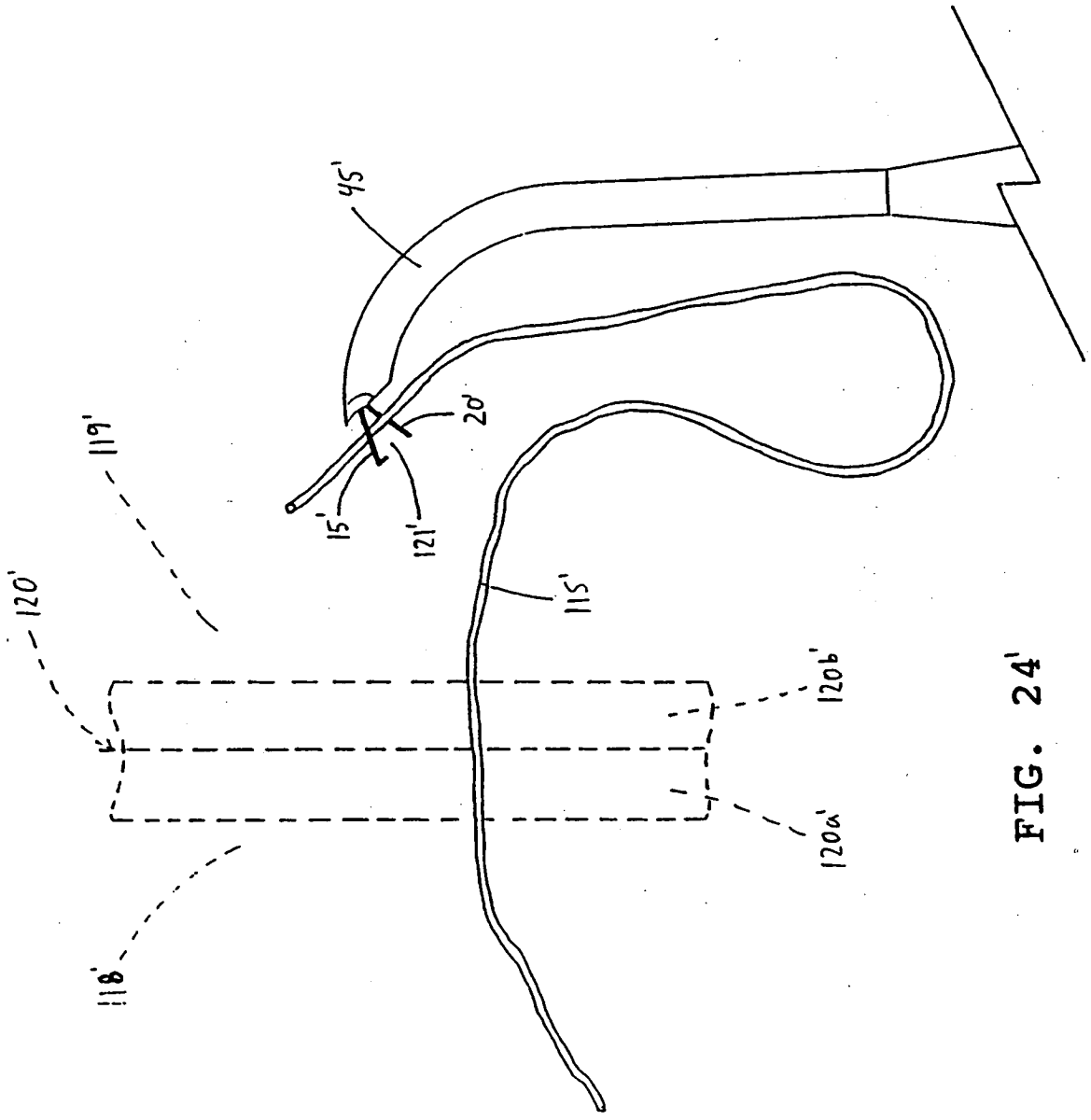


FIG. 24'

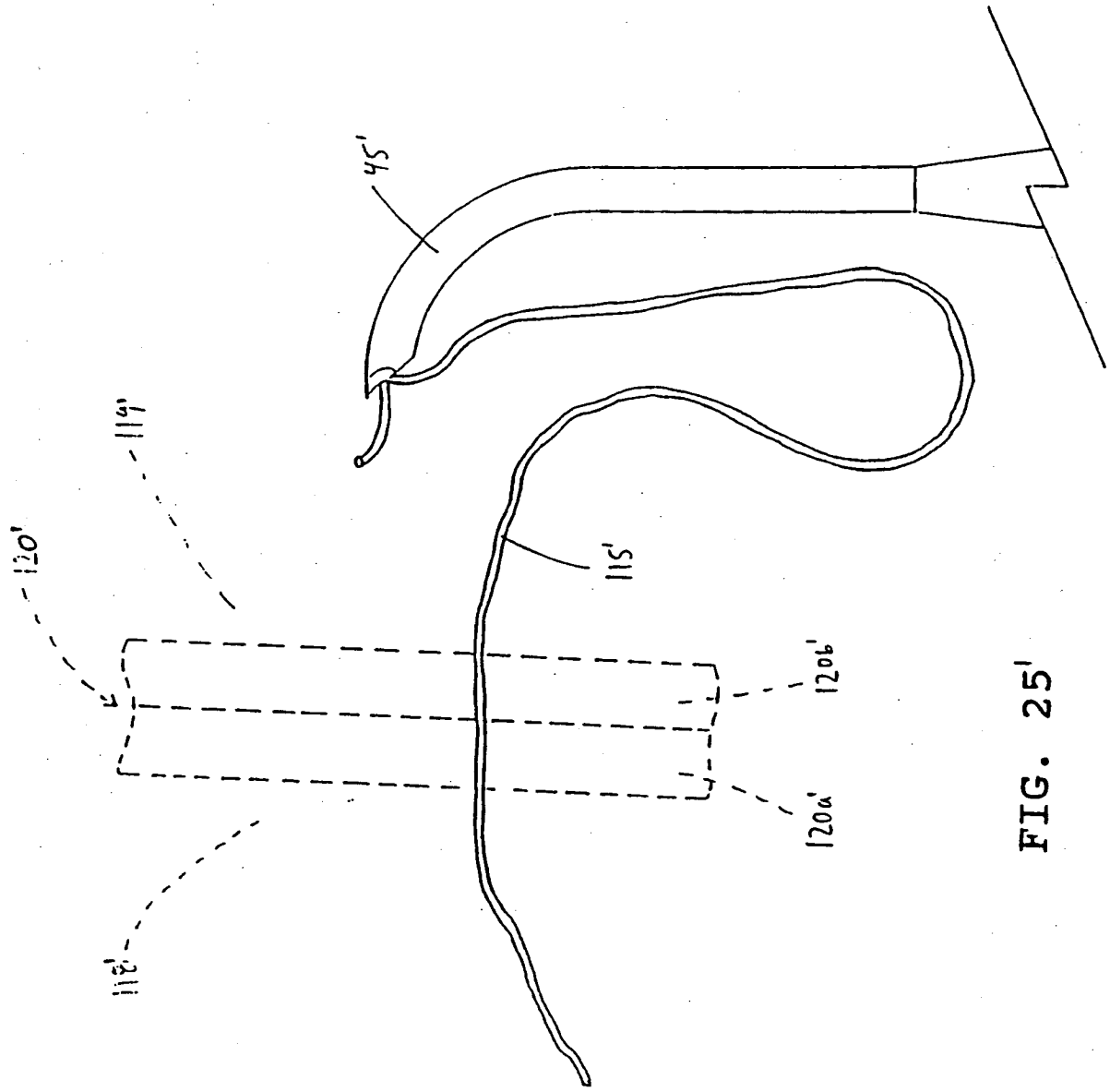


FIG. 25'

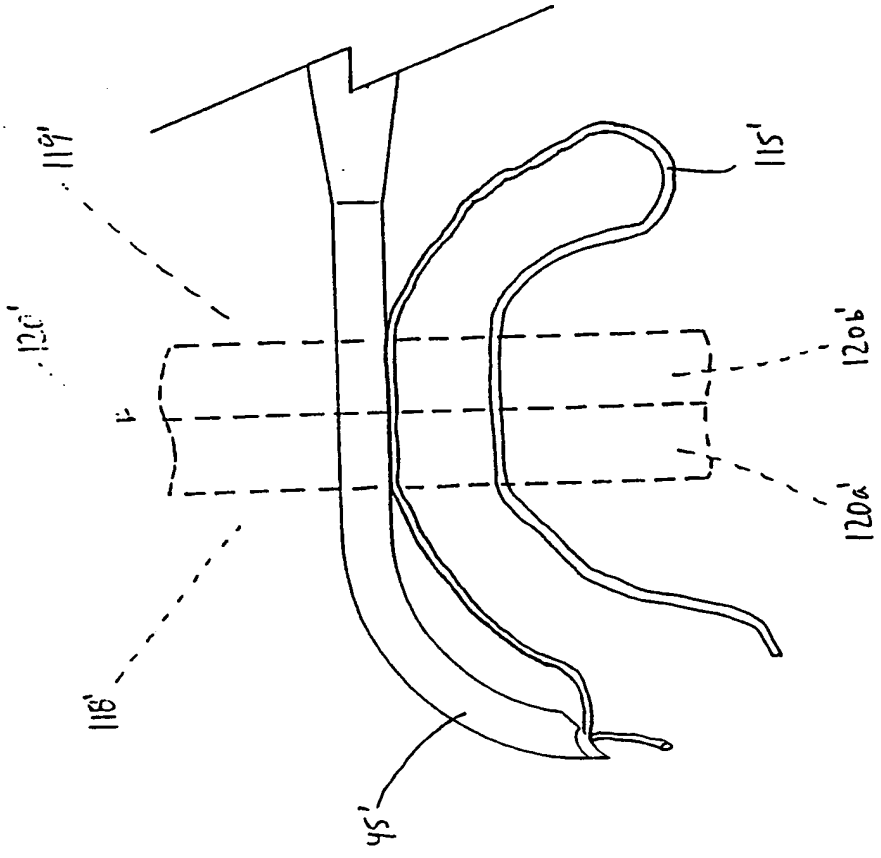


FIG. 26'

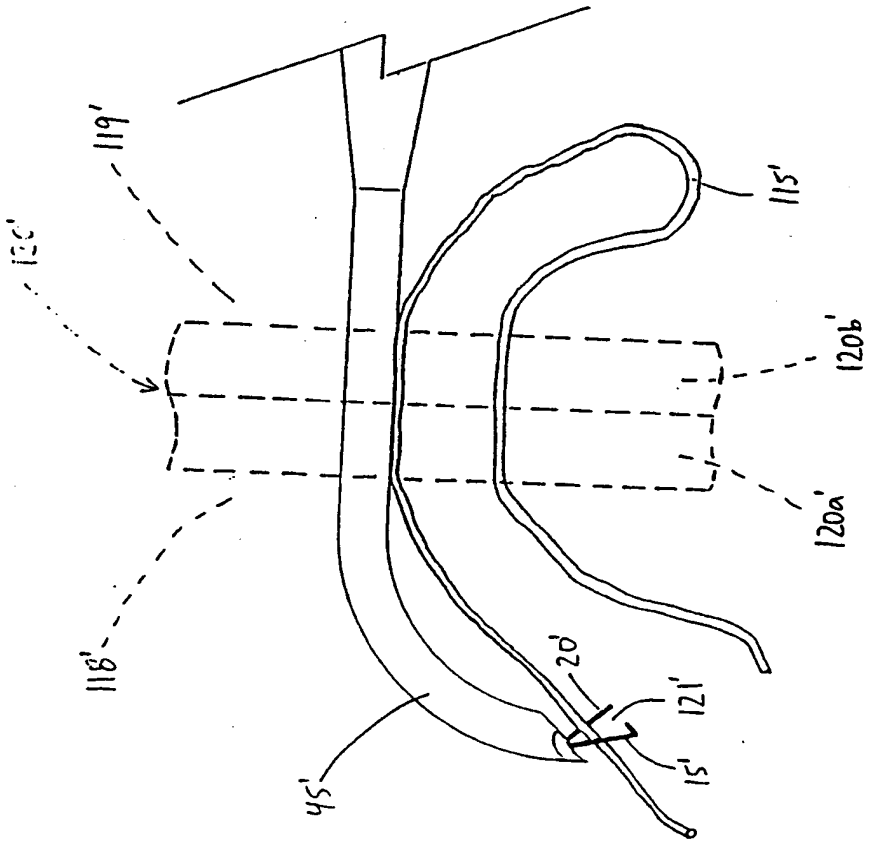


FIG. 27'

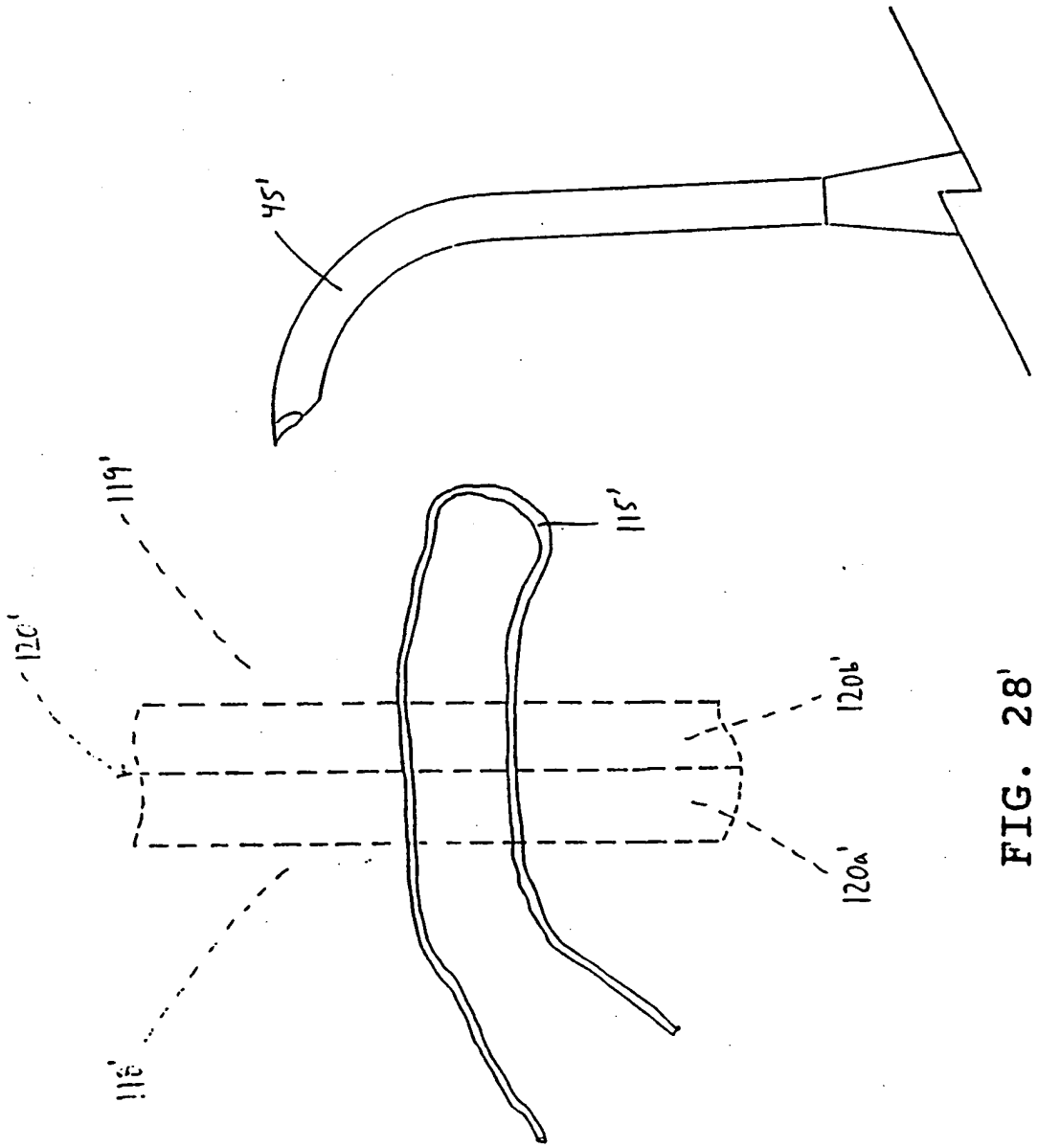


FIG. 28'

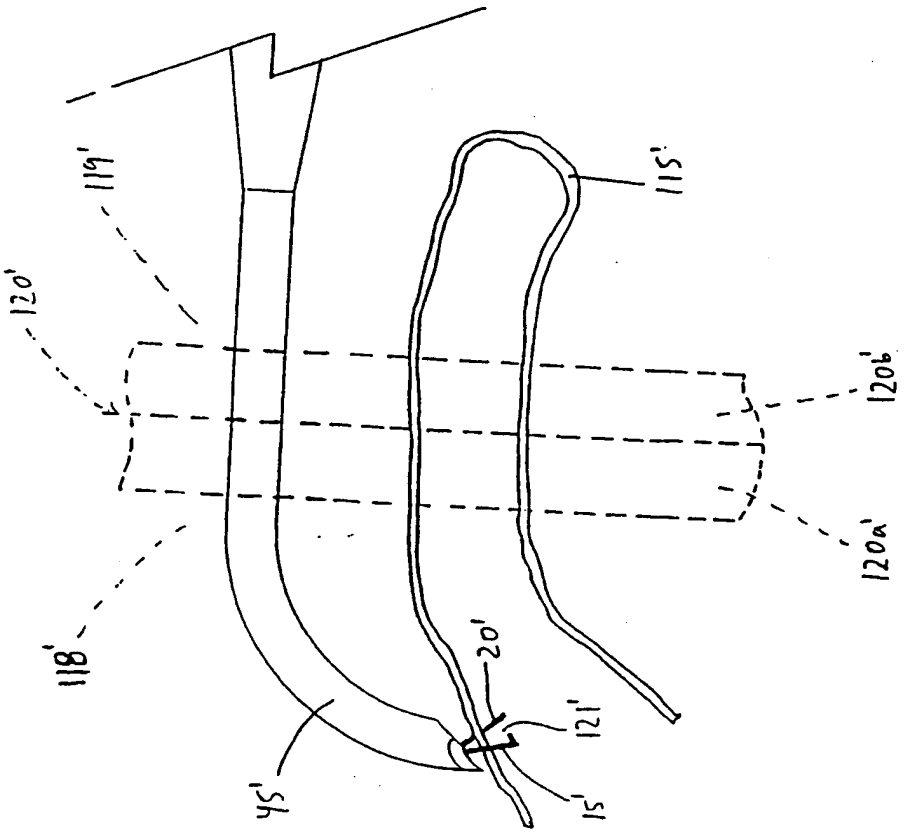


FIG. 29'

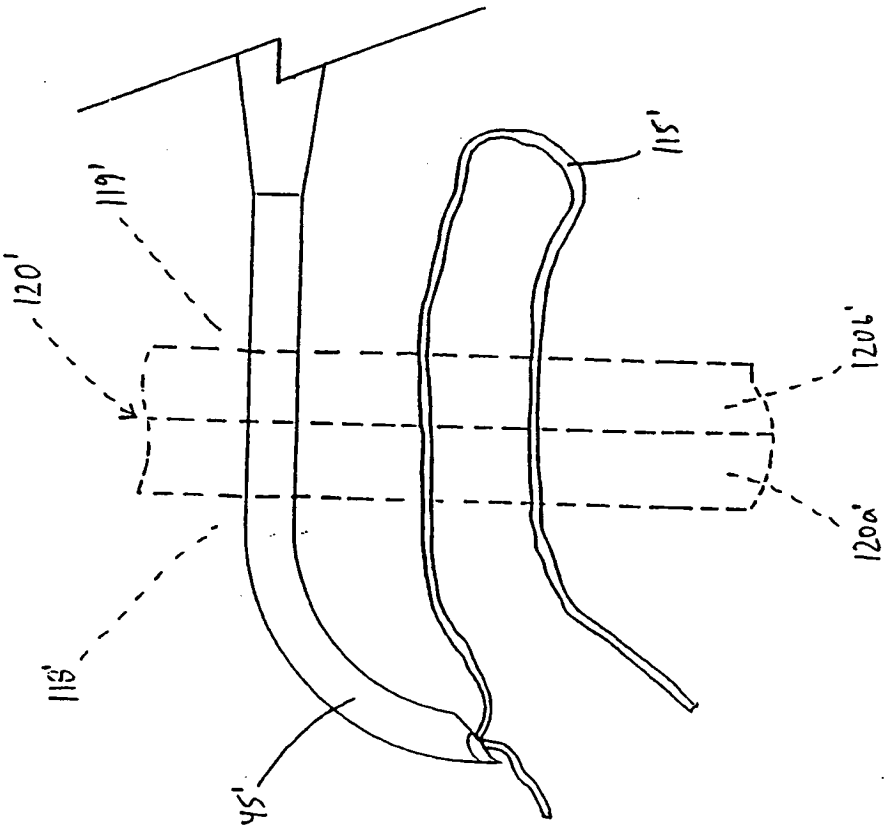


FIG. 30'

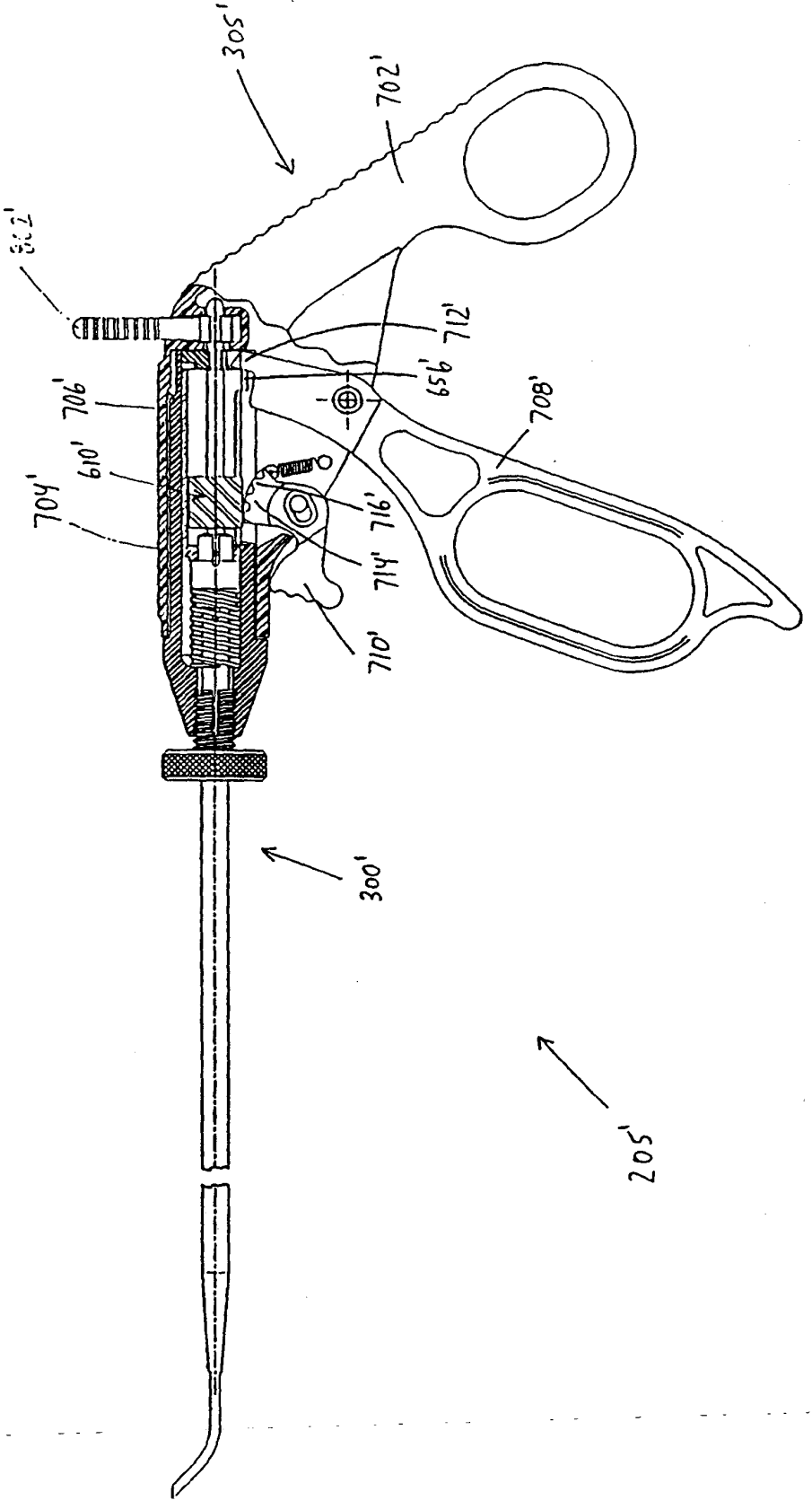


FIG. 33'

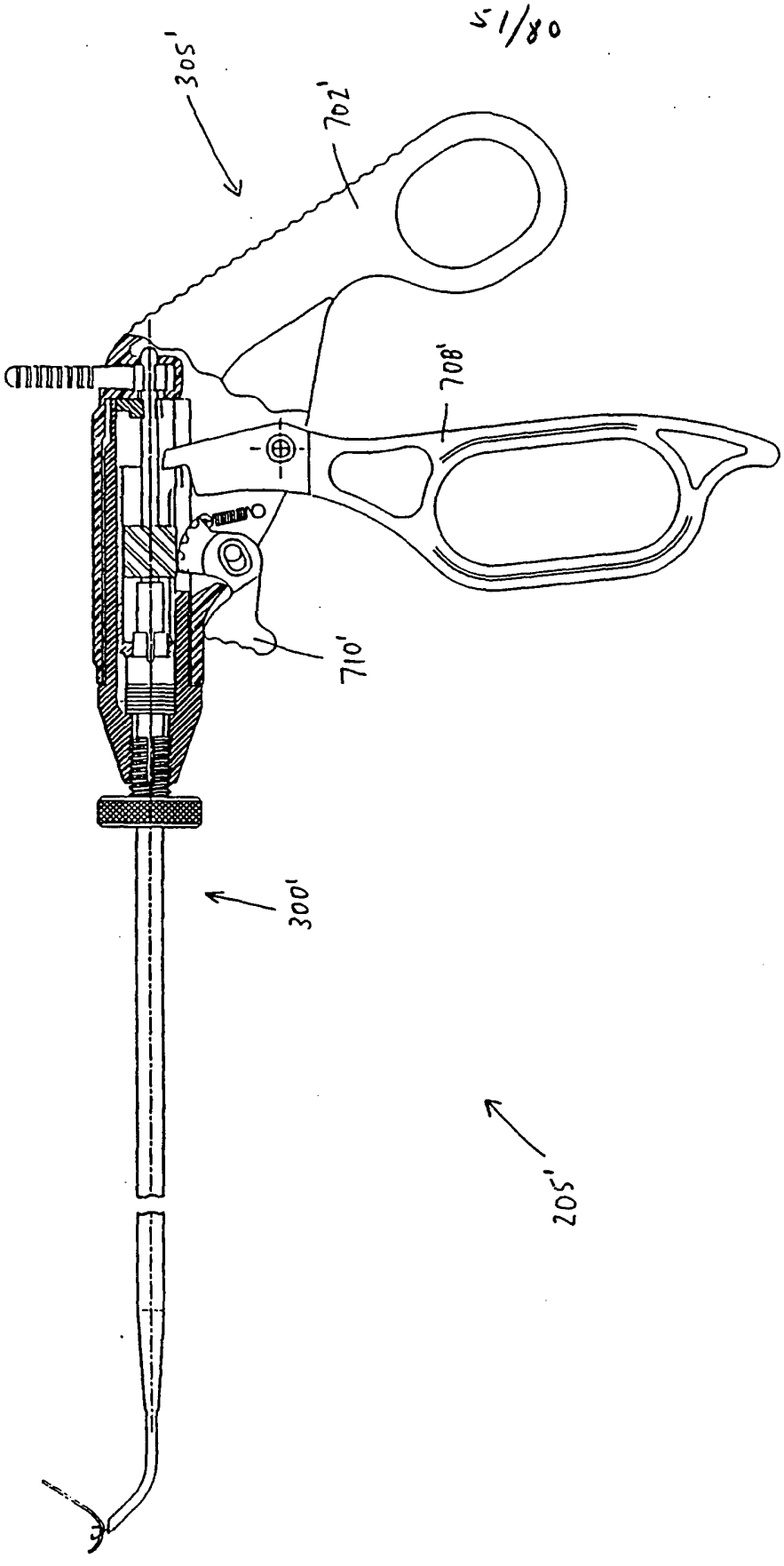


FIG. 34'

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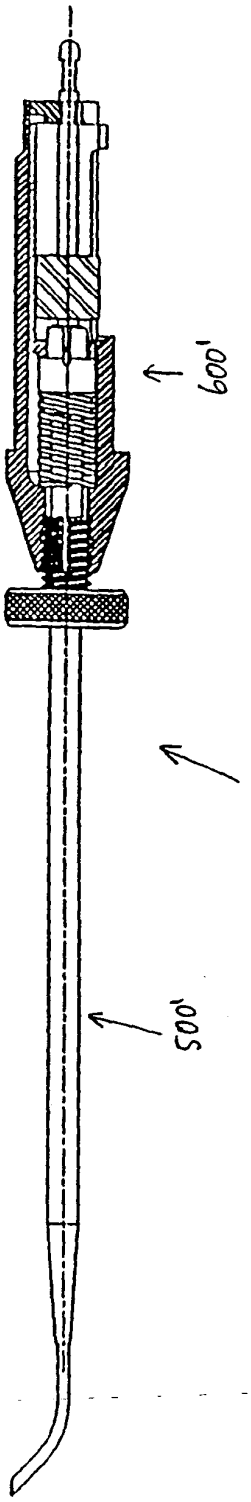

FIG. 35'

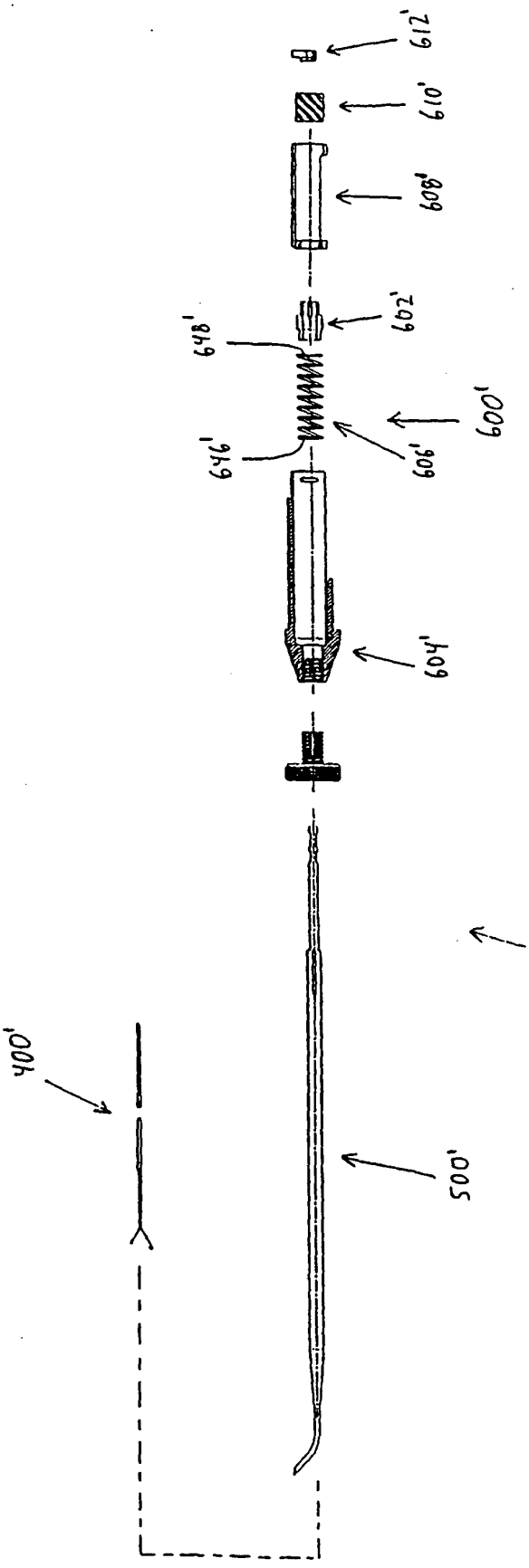

FIG. 36'

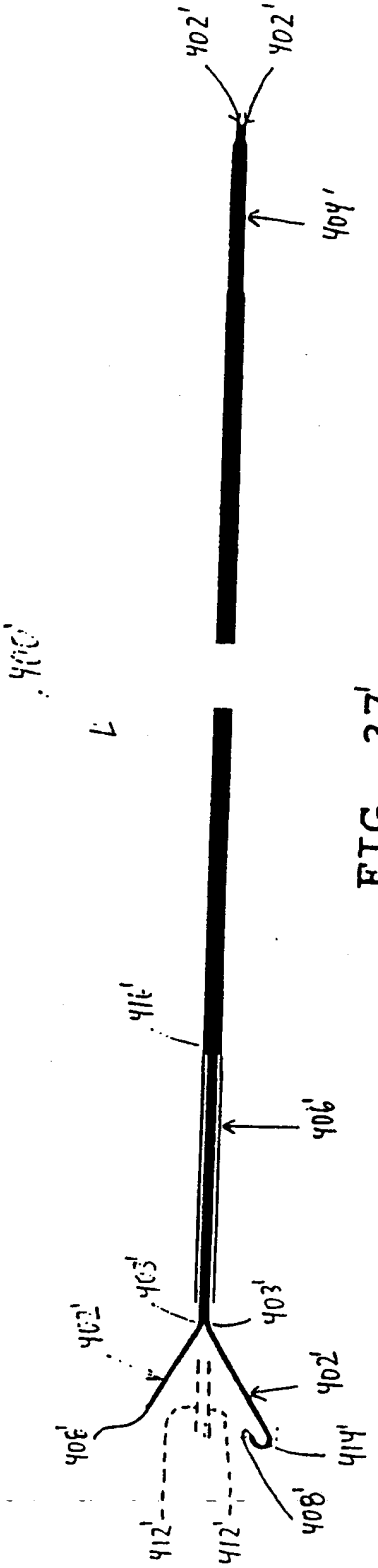

FIG. 37'

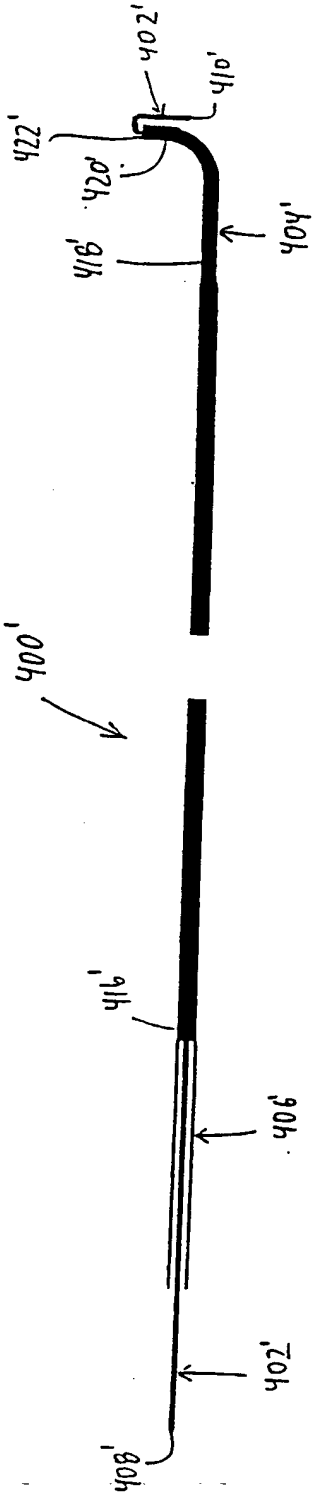

FIG. 38'

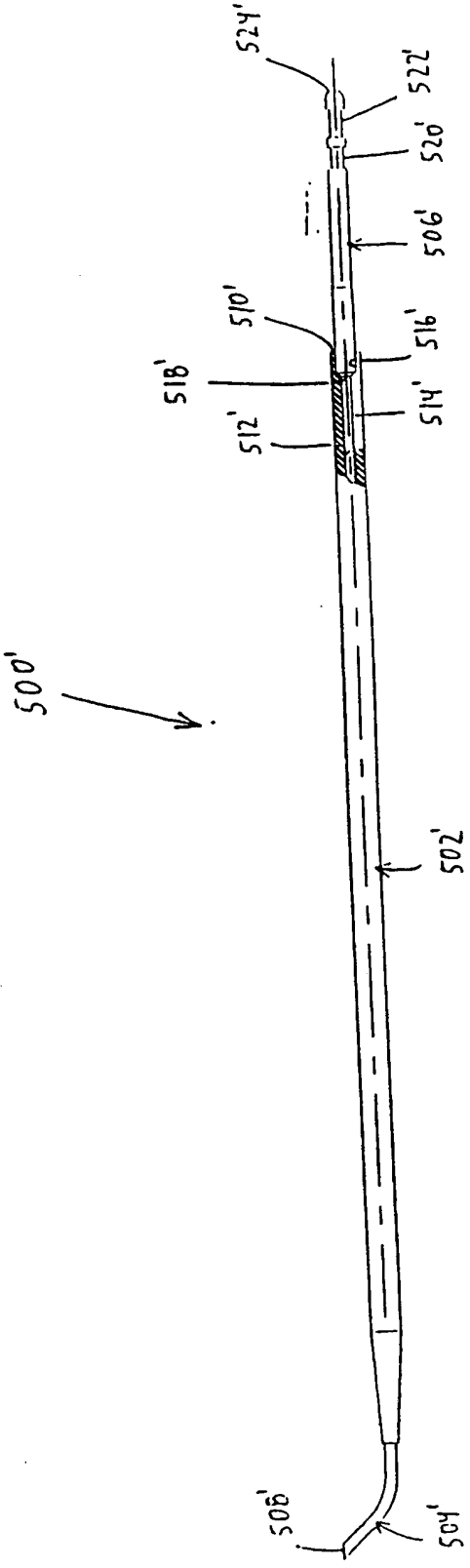

FIG. 39'

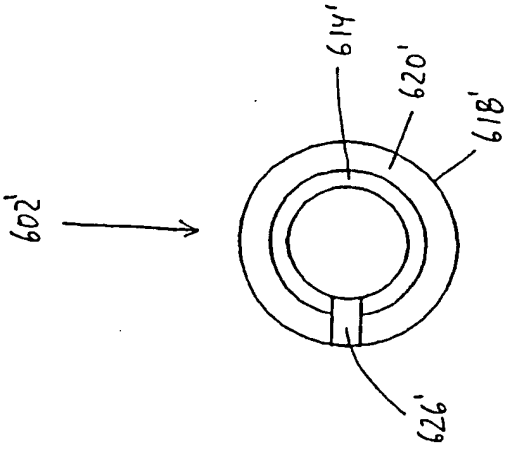

FIG. 42'

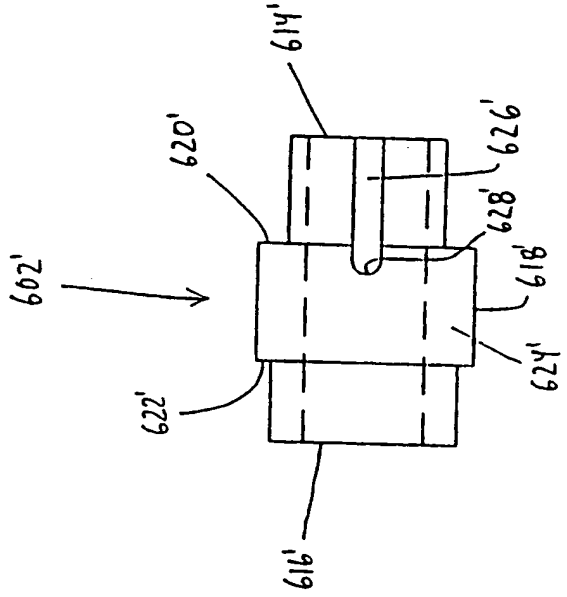

FIG. 40'

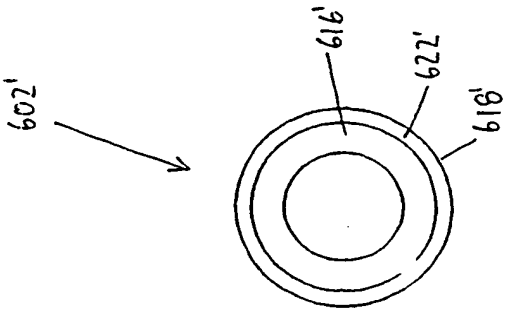

FIG. 41'

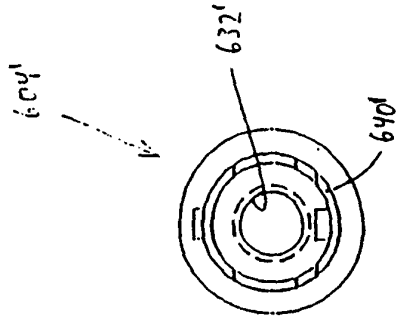

FIG. 45'

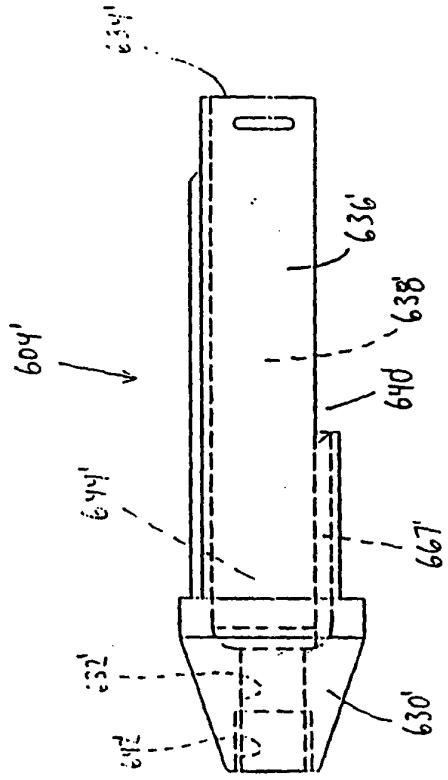

FIG. 43'

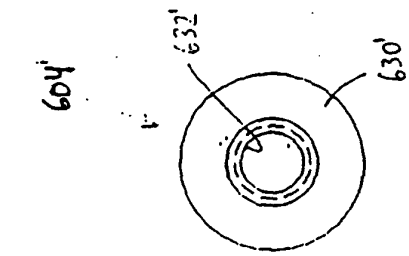

FIG. 44'

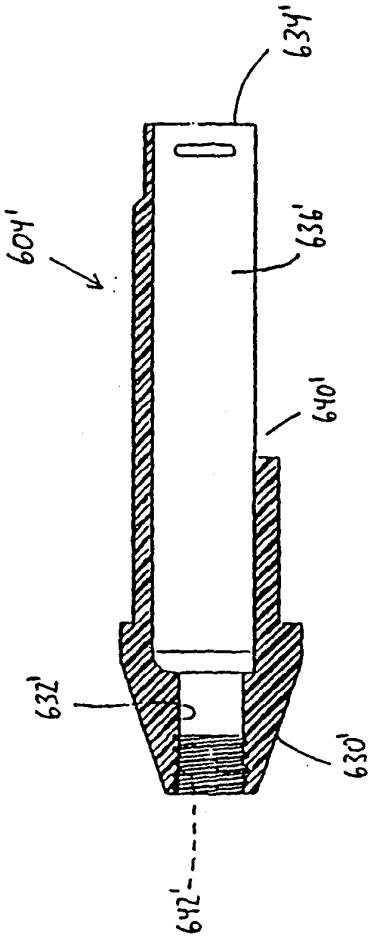

FIG. 46'

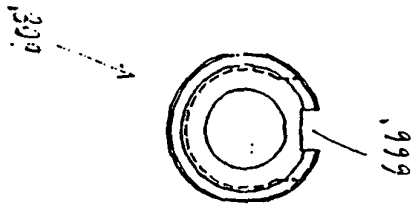

FIG. 49

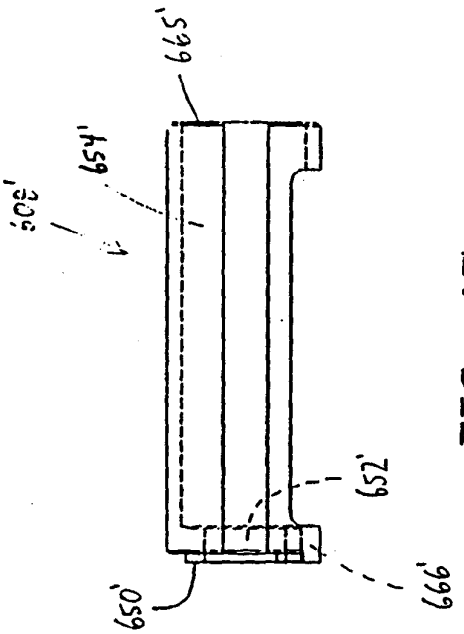

FIG. 47

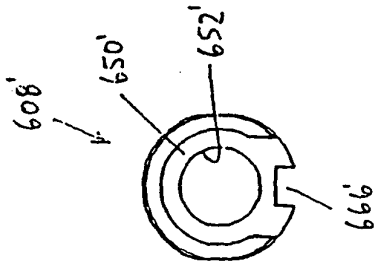

FIG. 48

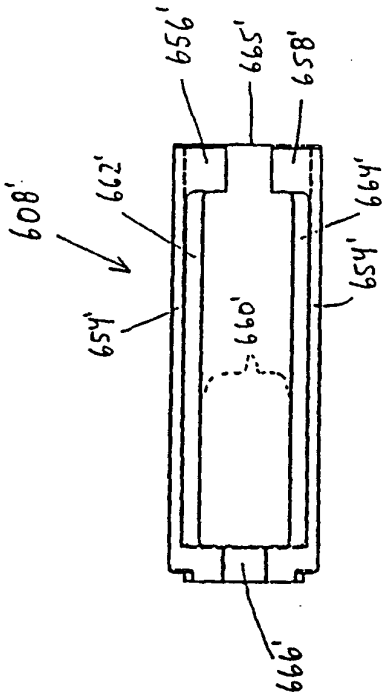

FIG. 50

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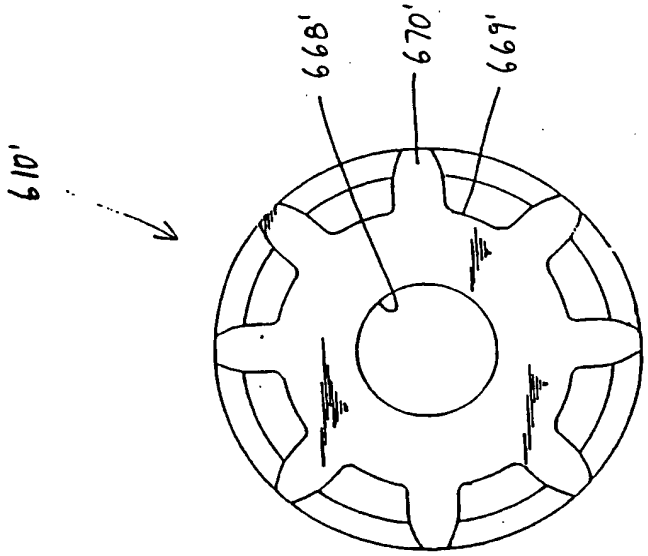

FIG. 52'

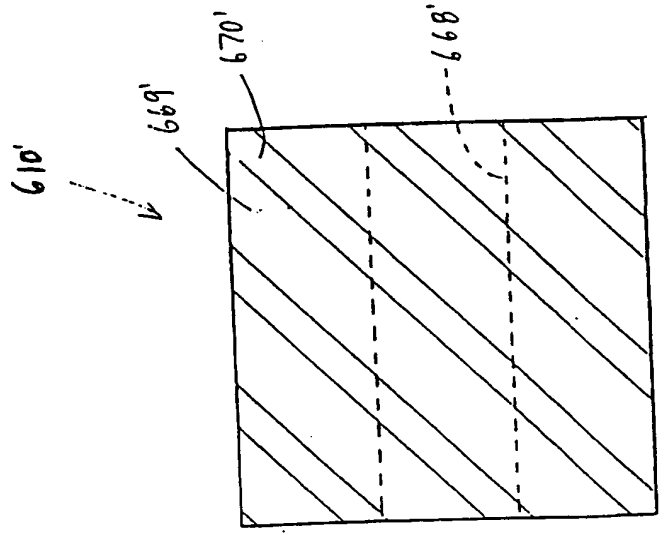

FIG. 51'

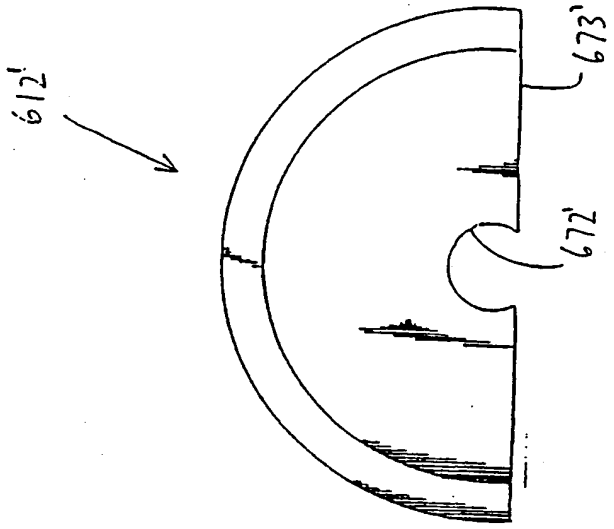

FIG. 54'

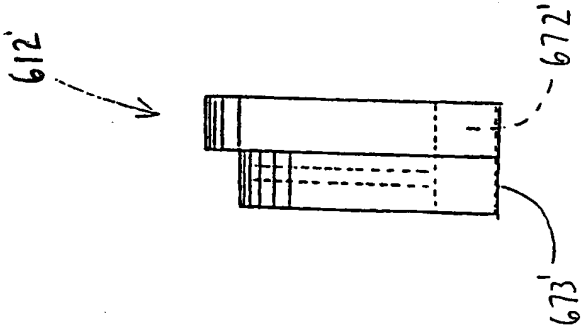

FIG. 53'

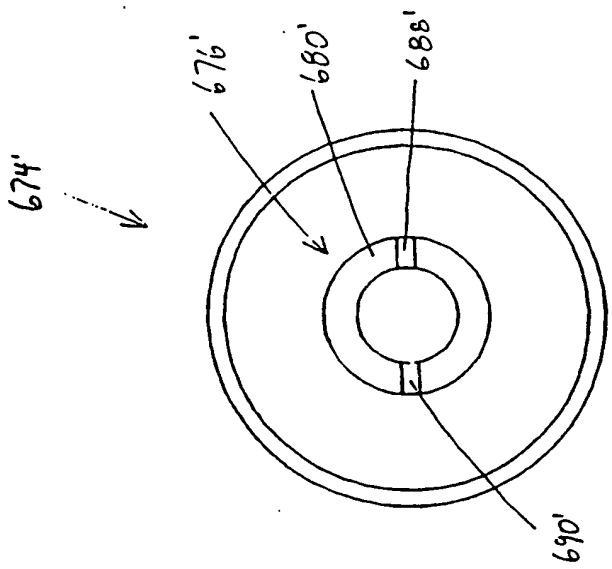

FIG. 57'

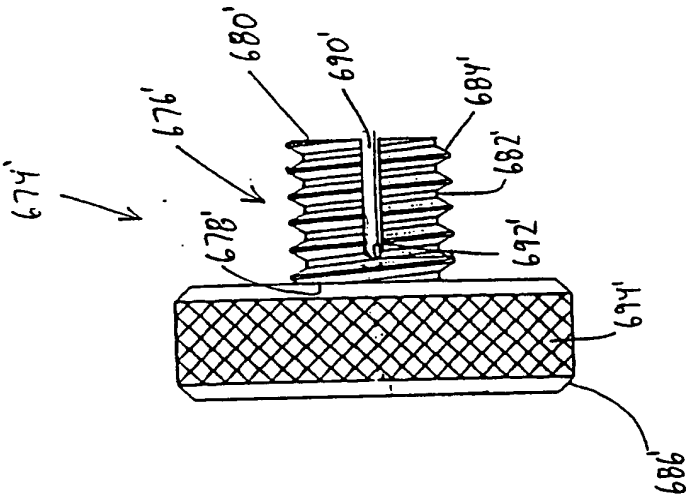

FIG. 55'

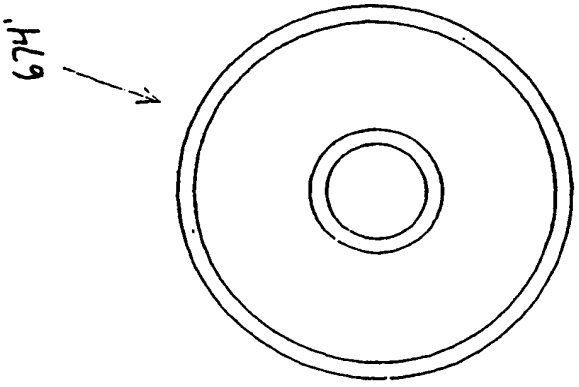

FIG. 56'

FIG. 58'

FIG. 59'

FIG. 60'

FIG. 61'

FIG. 62'

FIG. 63'

FIG. 64'

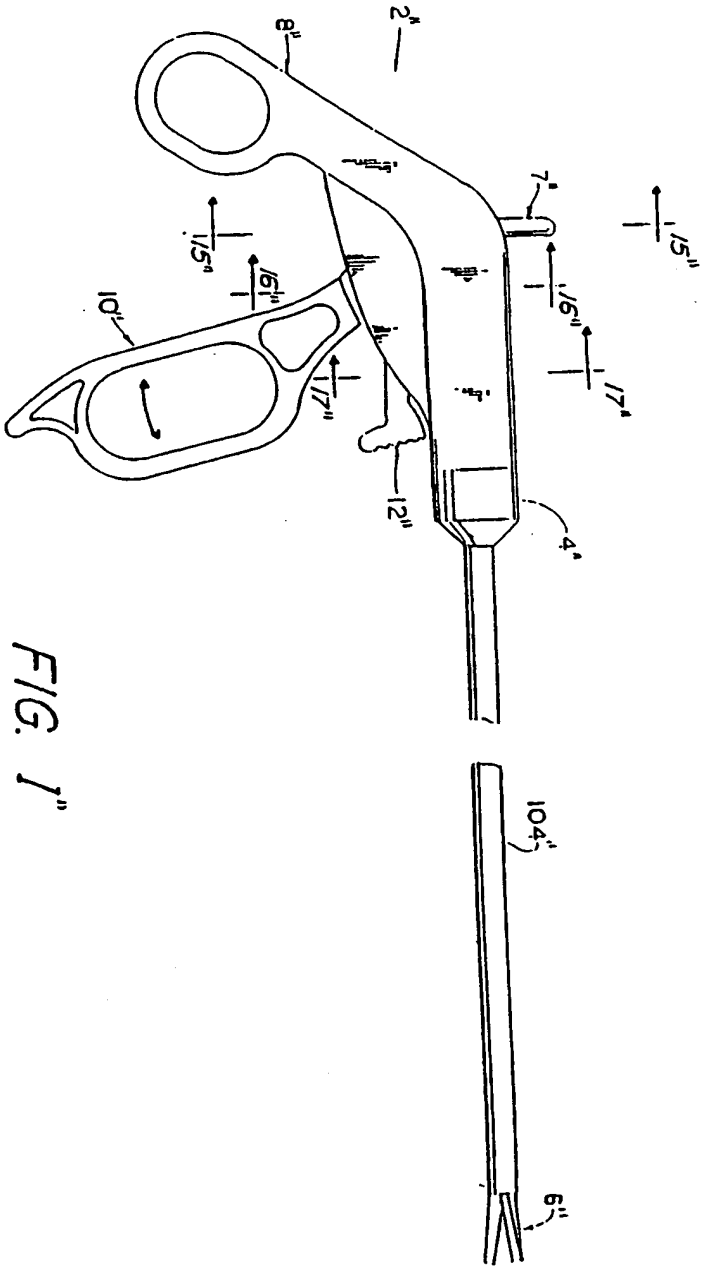

FIG. 1"

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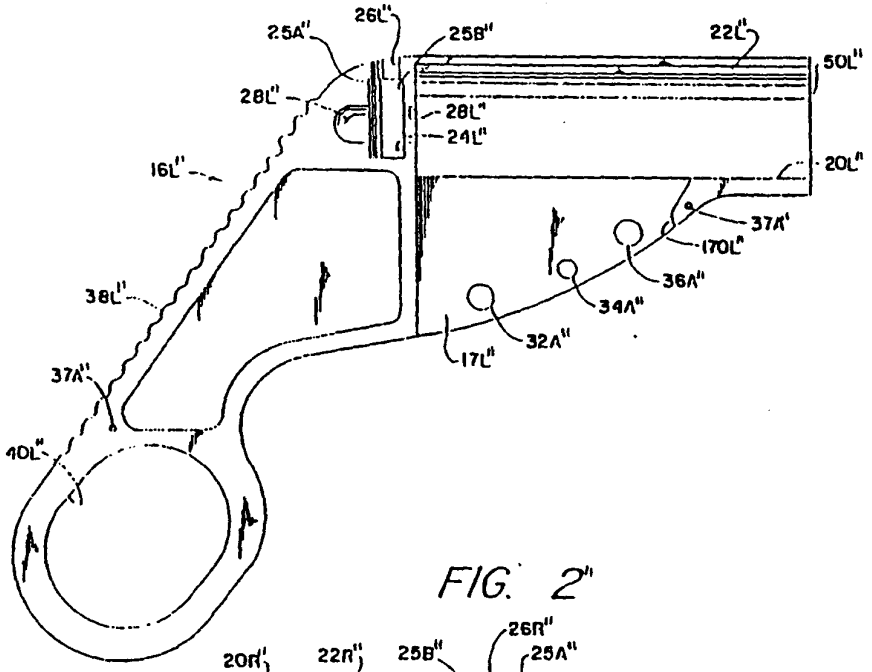

FIG. 2"

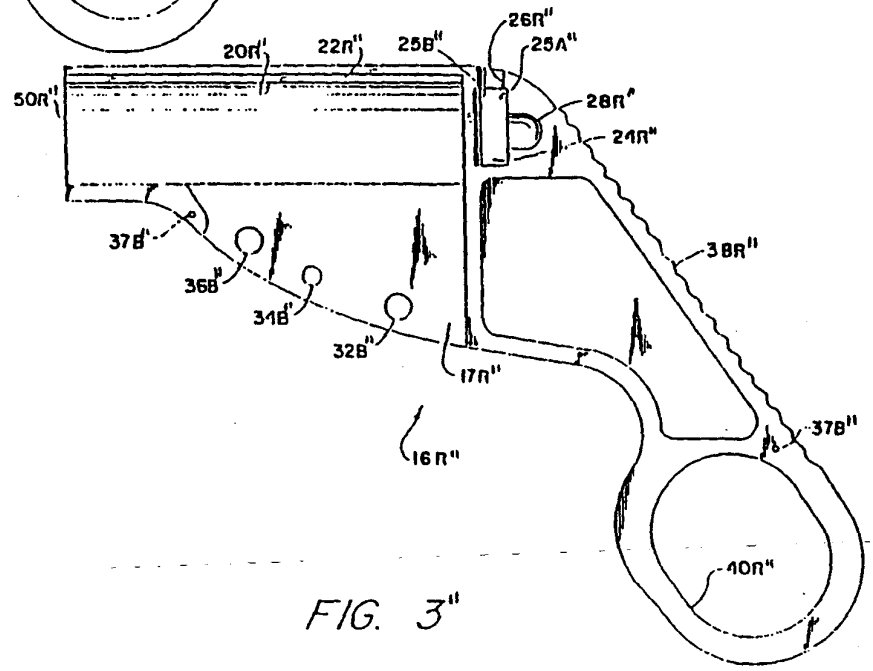

FIG. 3"

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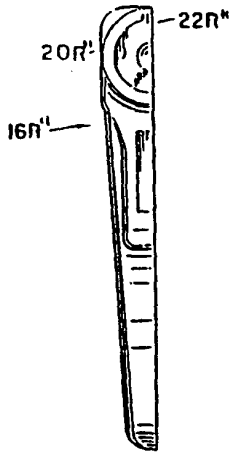
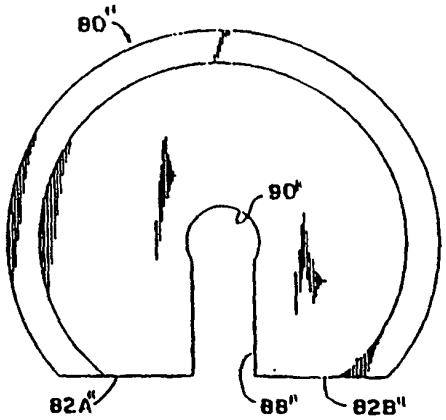


FIG. 4"



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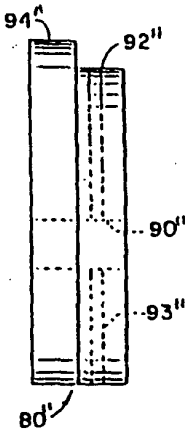


FIG. 9"

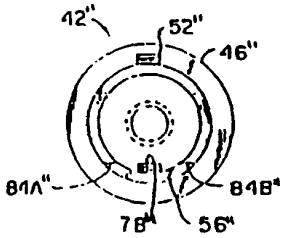
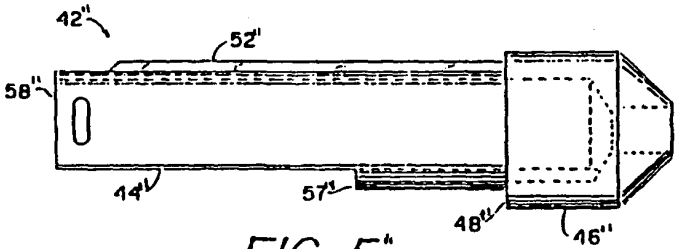


FIG. 7"



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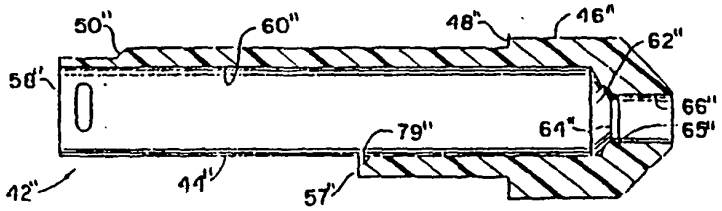

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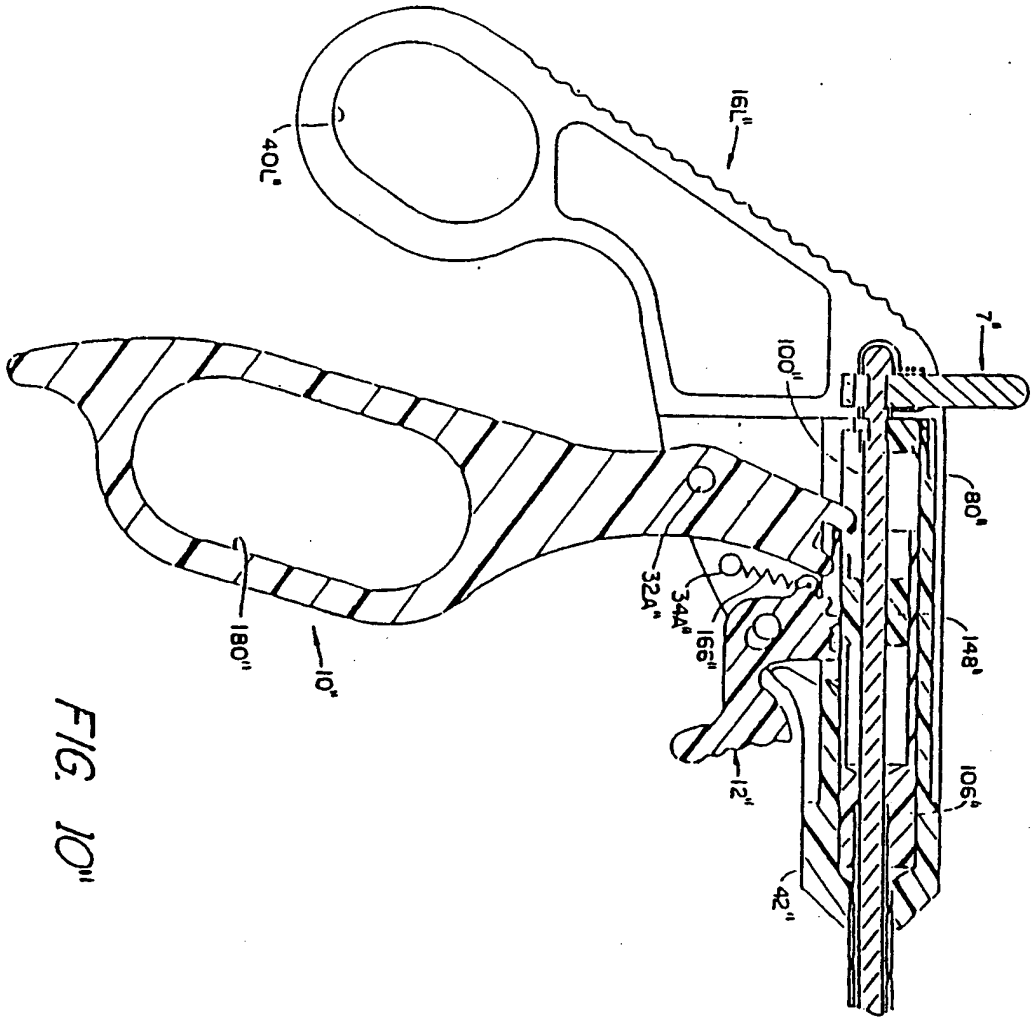

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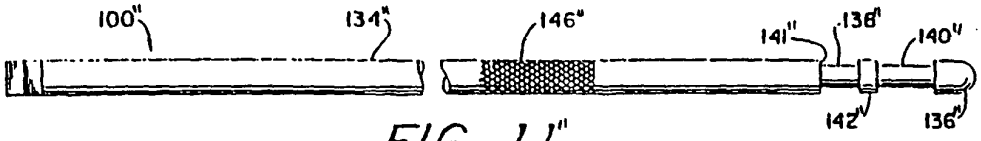
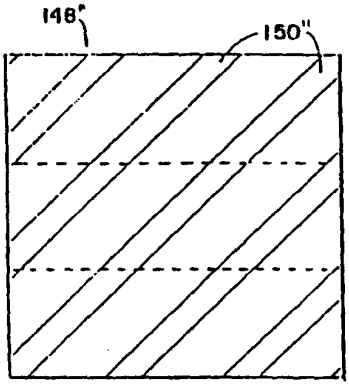


FIG. 11"

FIG. 12"



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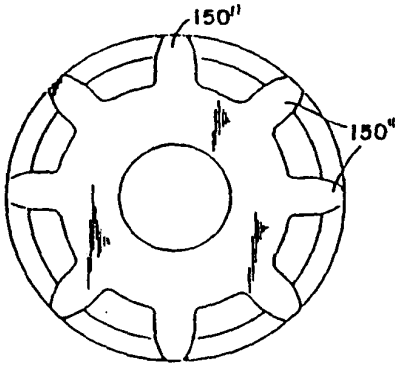

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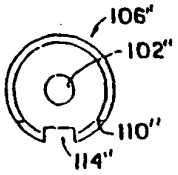

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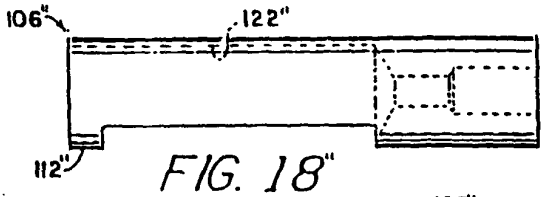

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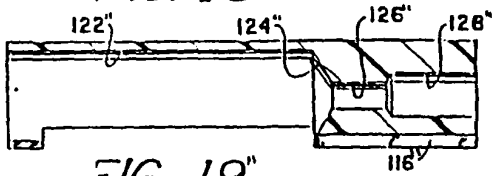

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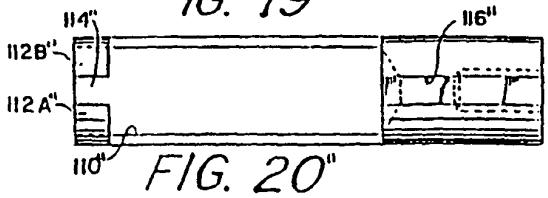

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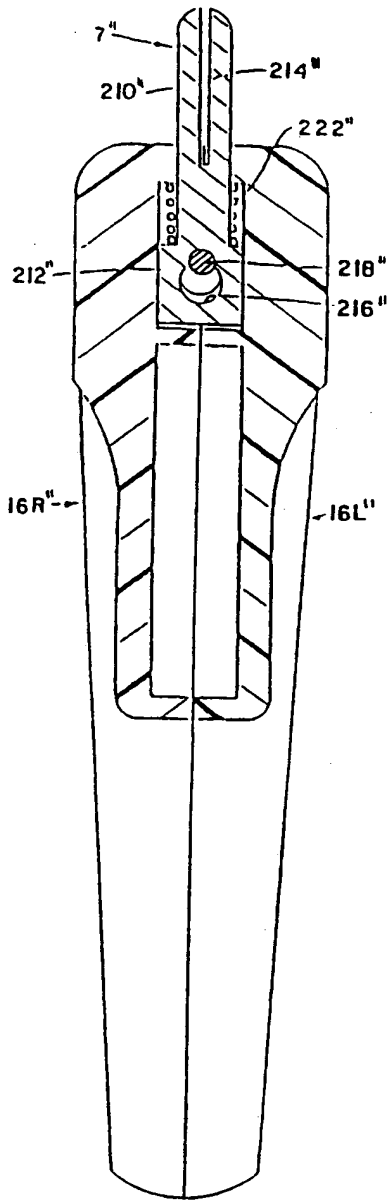


FIG. 15"

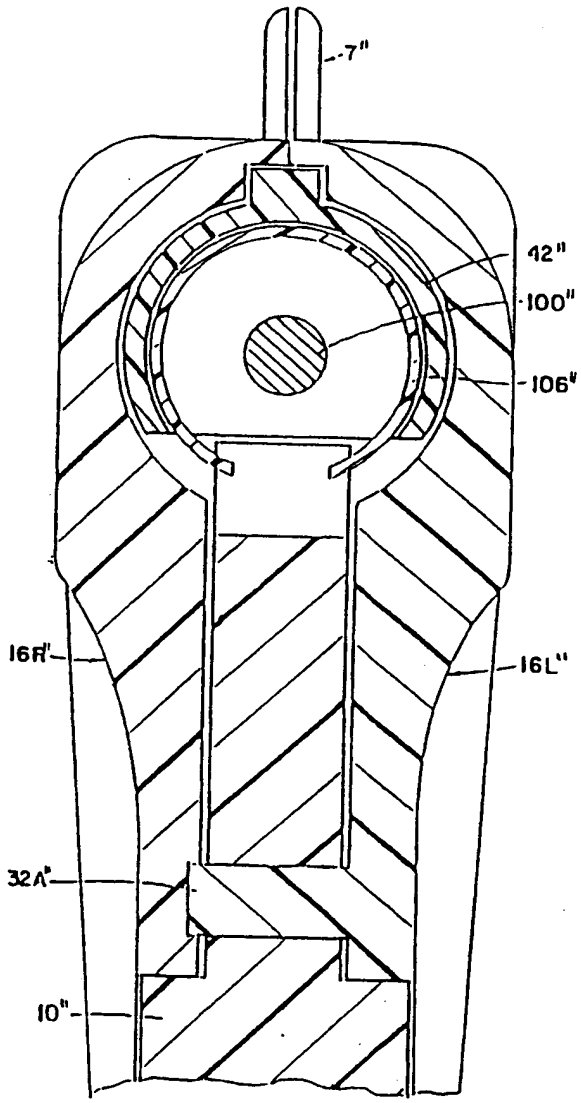


FIG. 16"

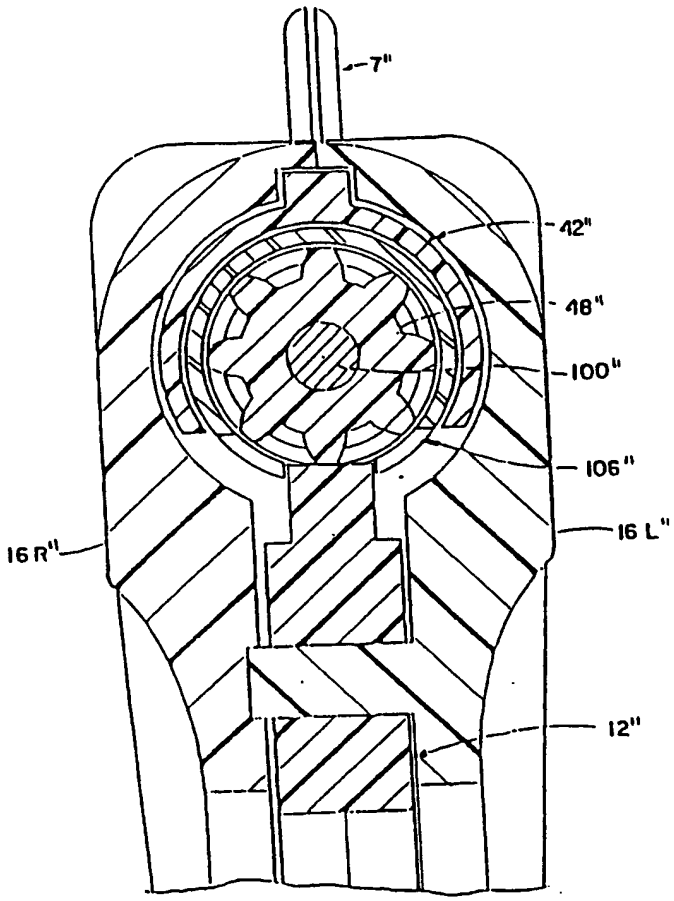
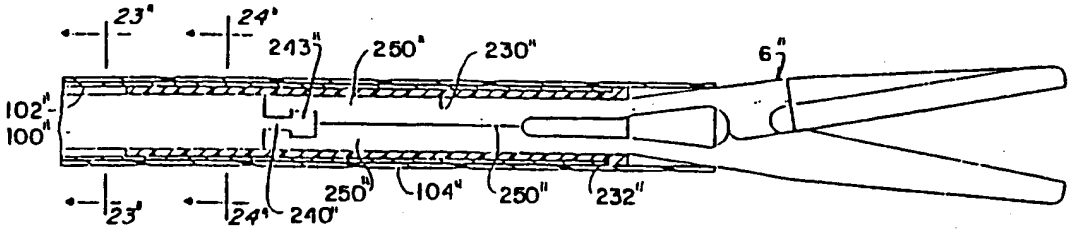


FIG. 17"



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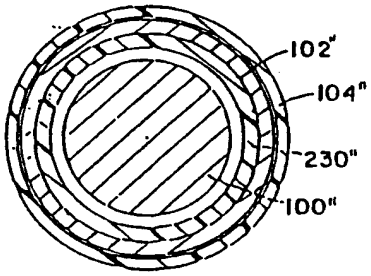

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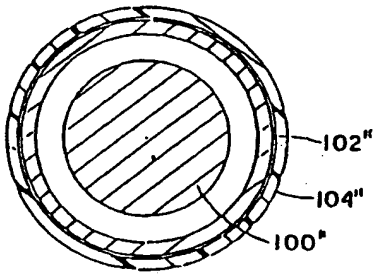
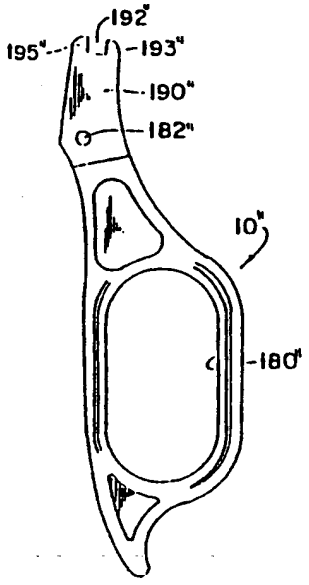


FIG. 23"



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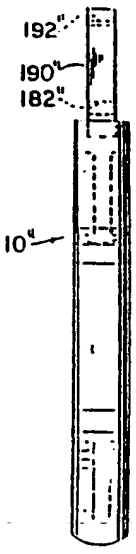
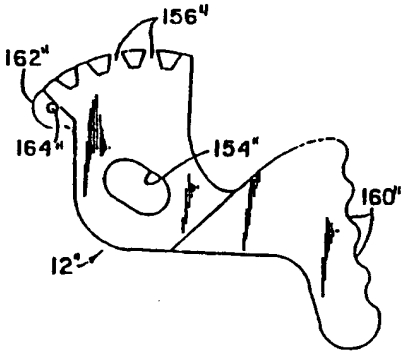


FIG. 26"



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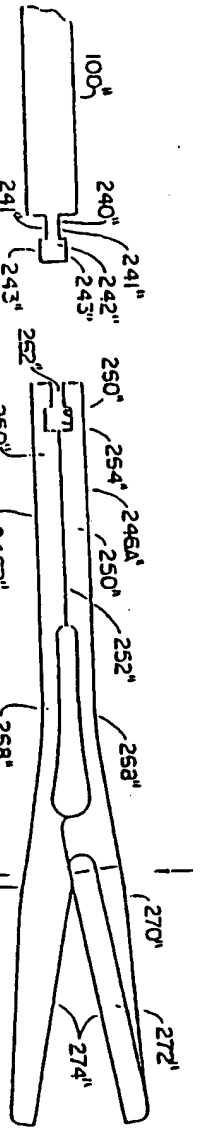

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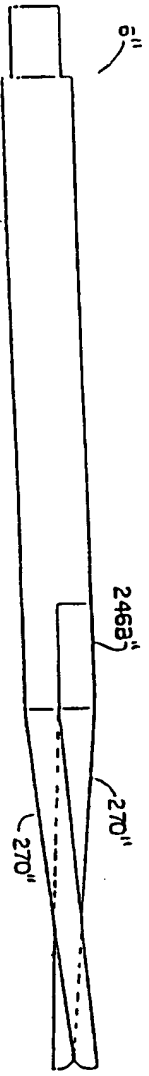

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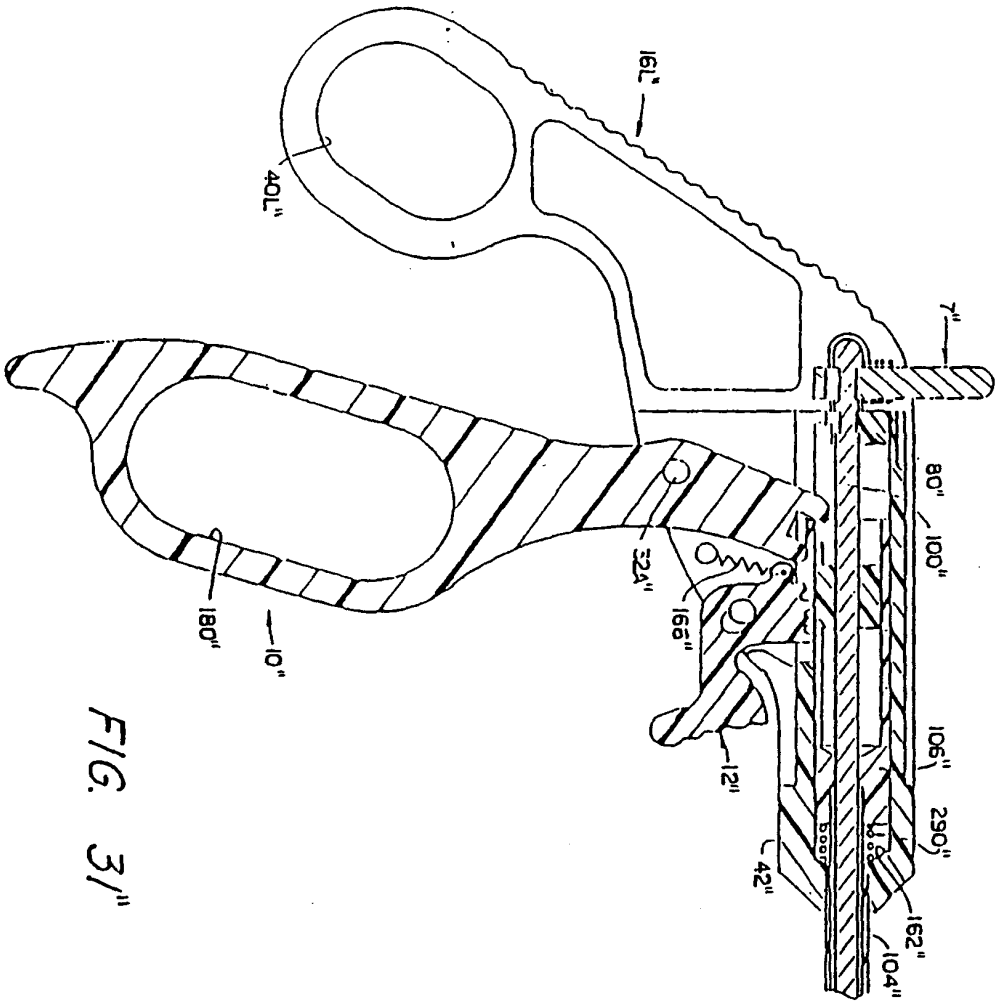

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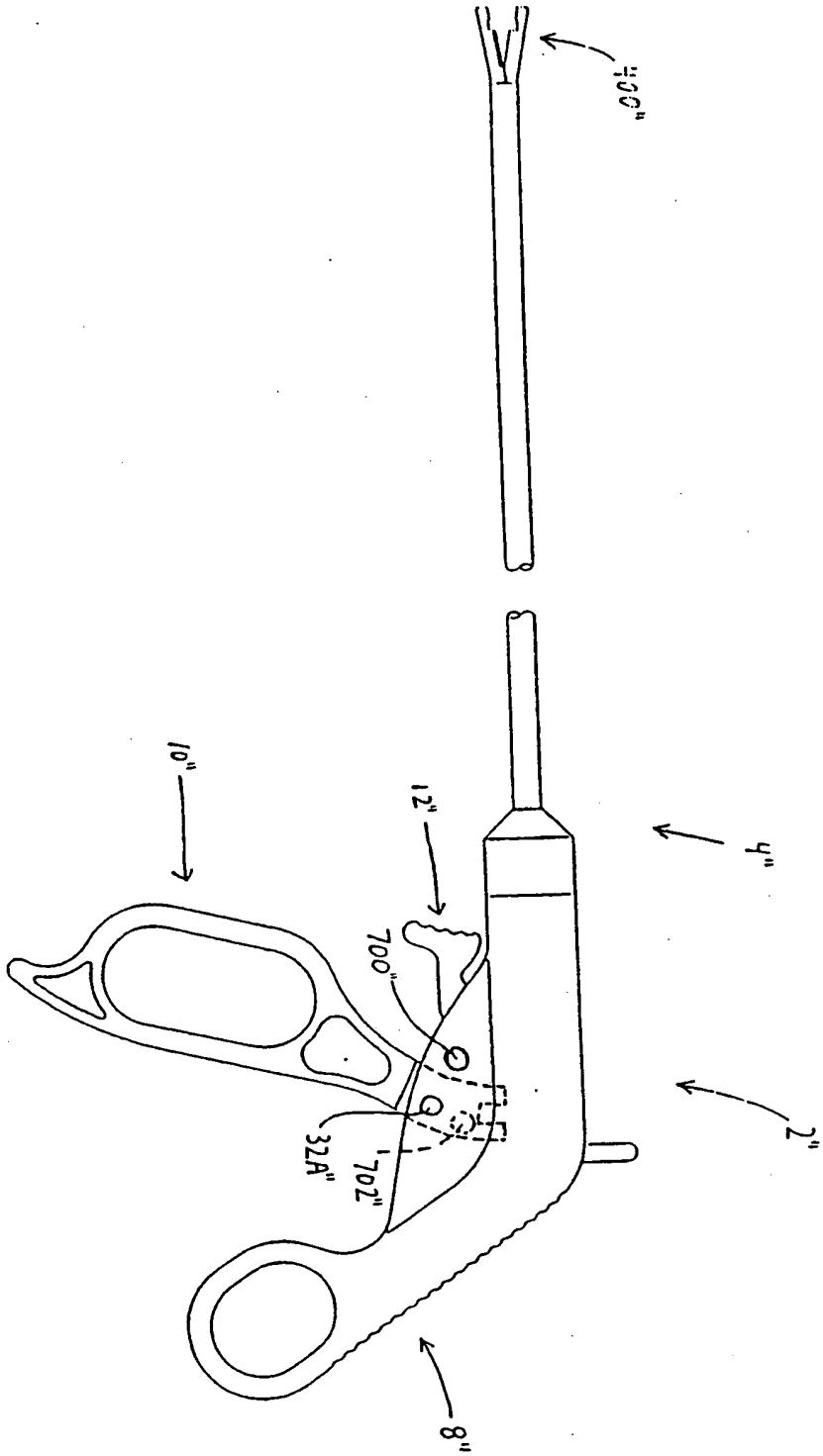

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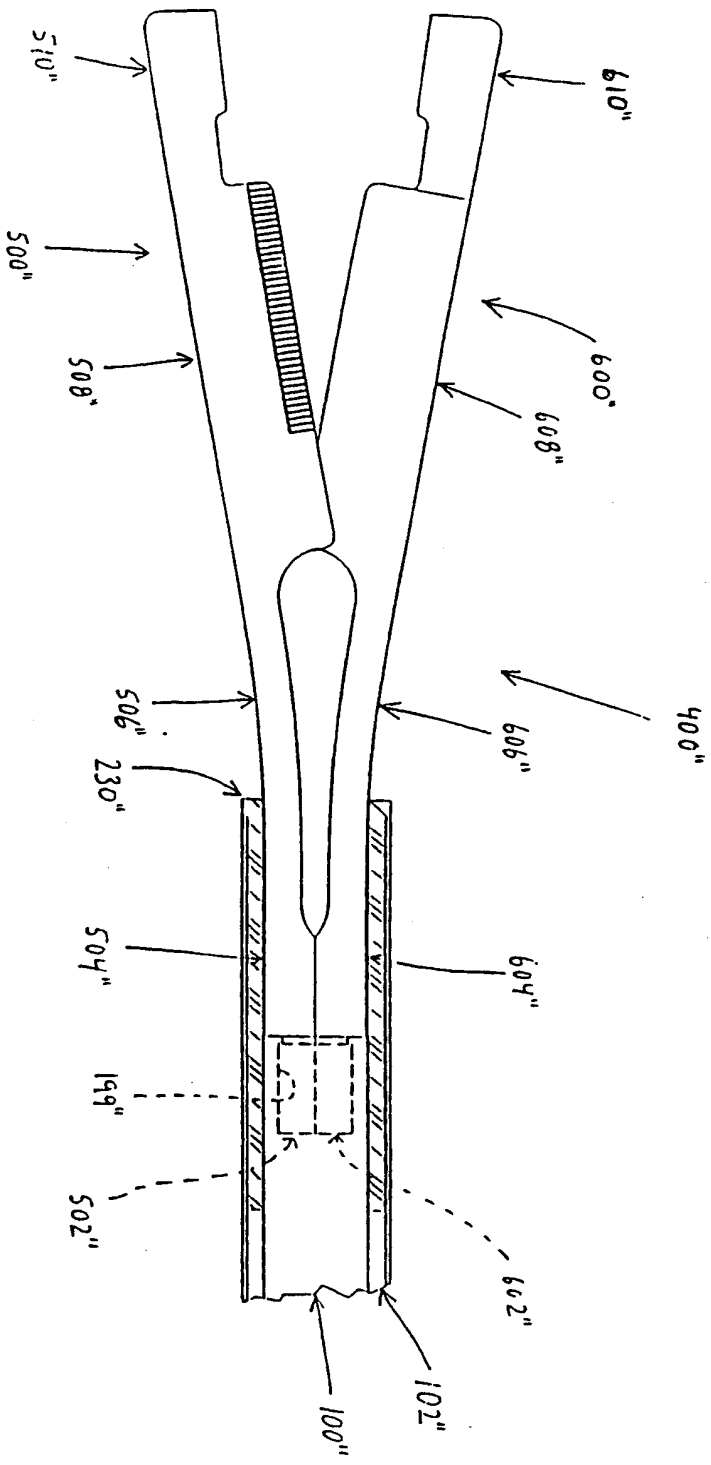

FIG. 33"

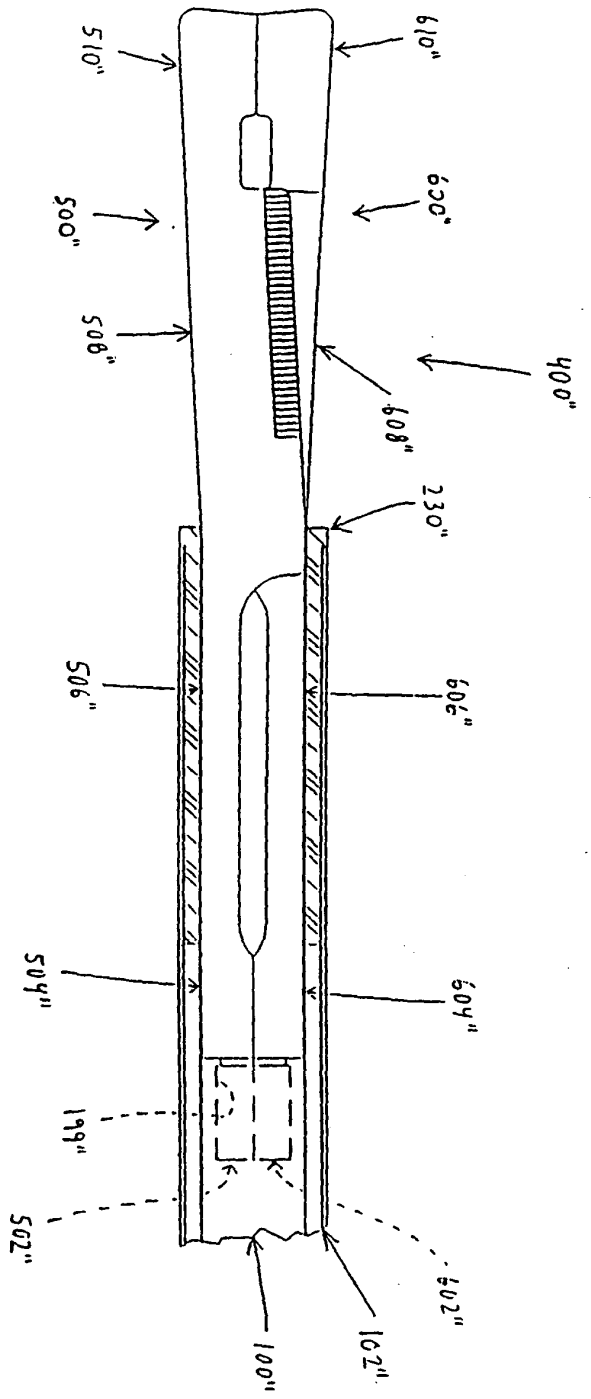
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FIG. 34"

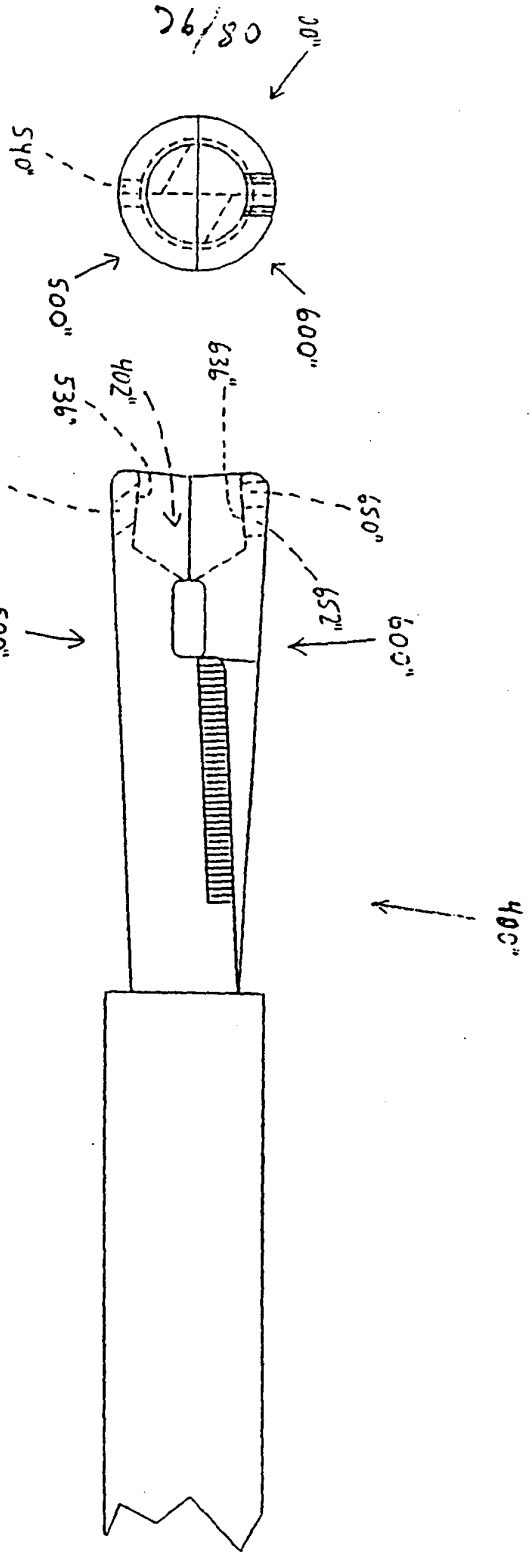


FIG. 36"

FIG. 35"

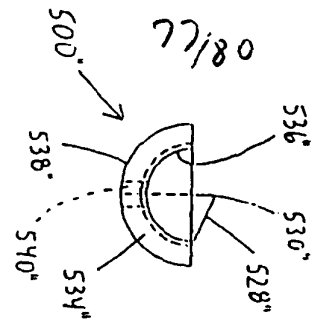
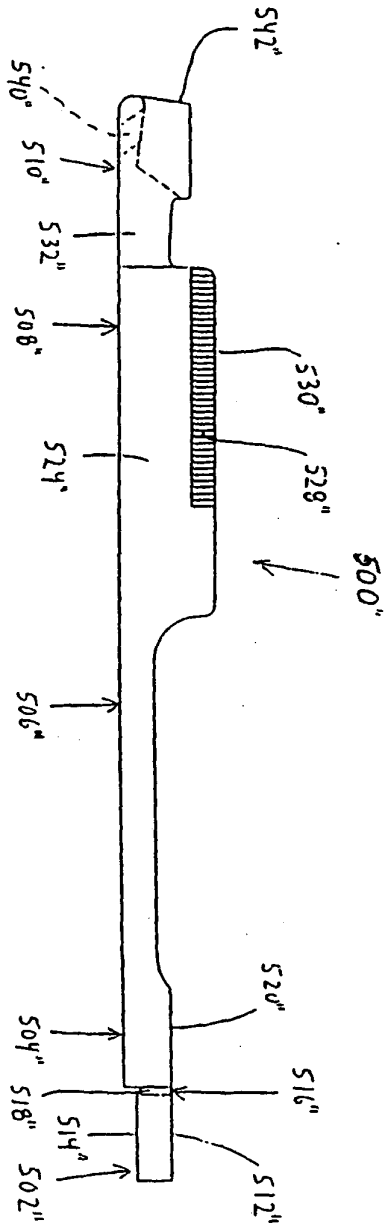


FIG. 39"



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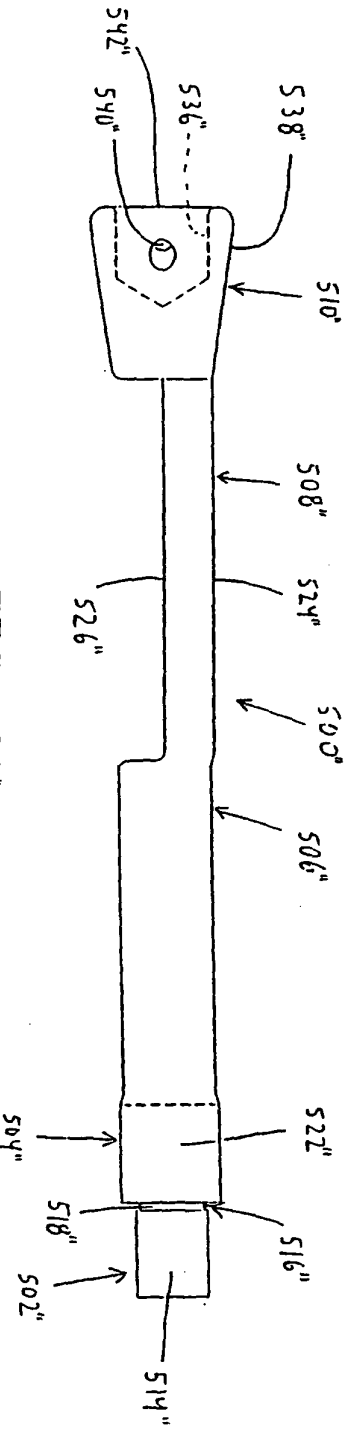

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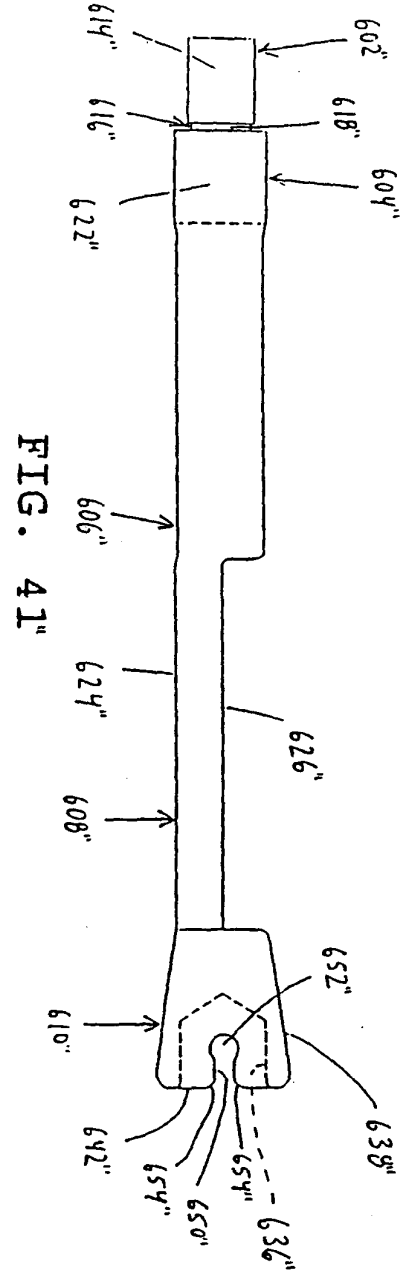

FIG. 41"

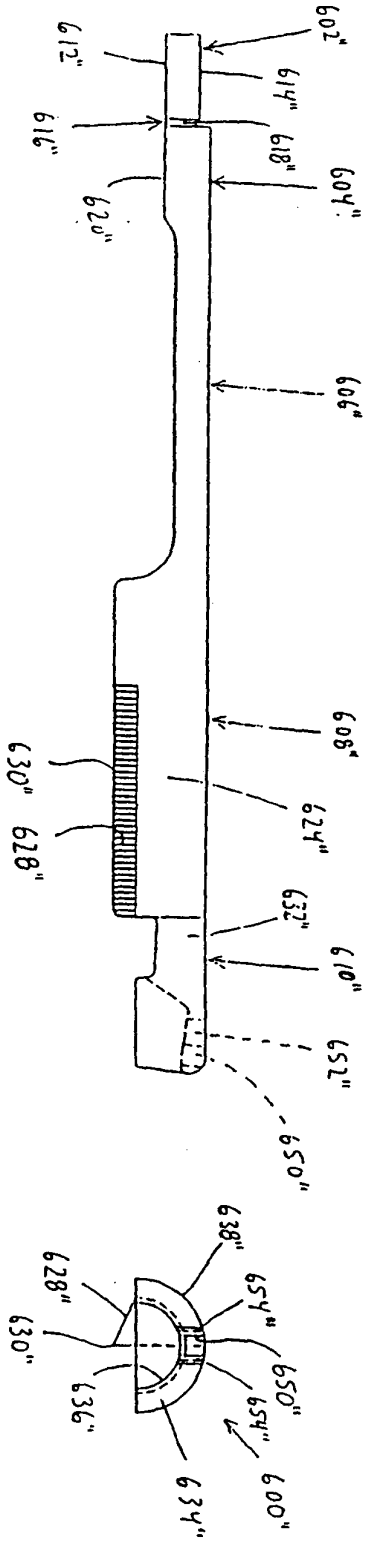

FIG. 40"

FIG. 42"

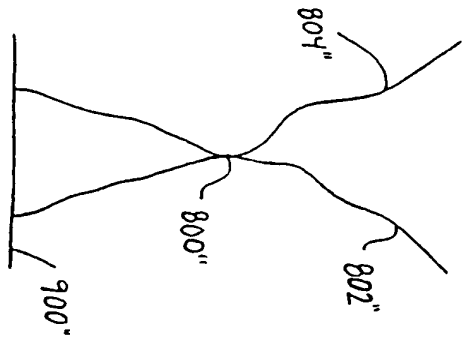

FIG. 43"

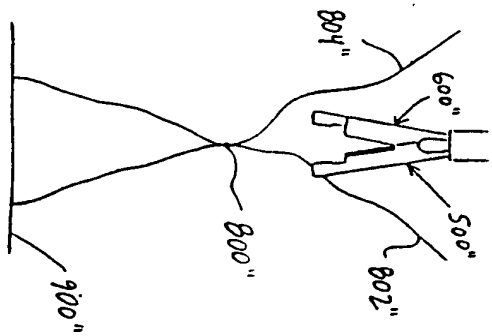

FIG. 44"

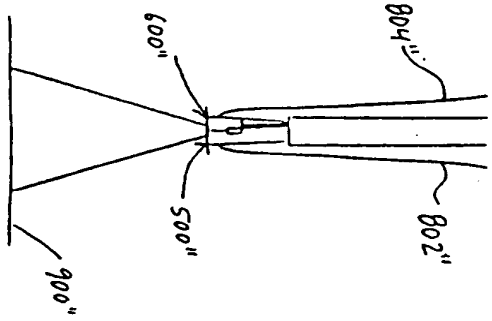

FIG. 45"

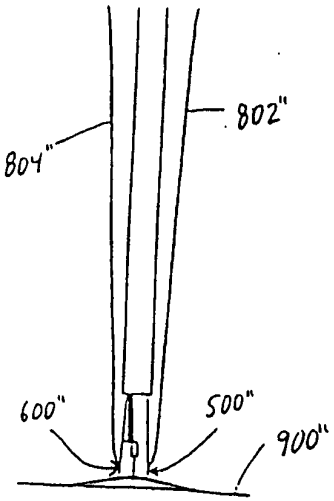

FIG. 46"

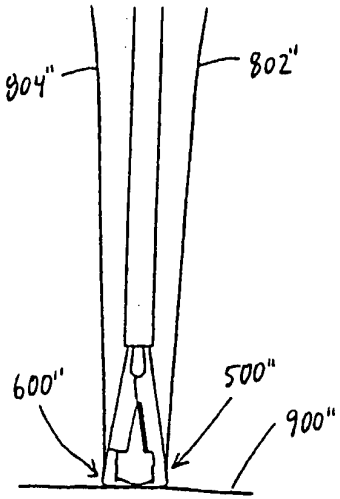

FIG. 47"

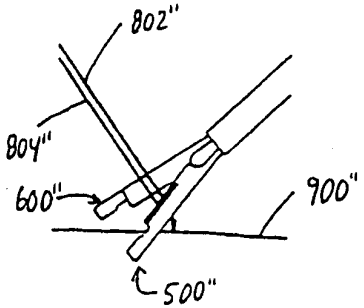

FIG. 48"

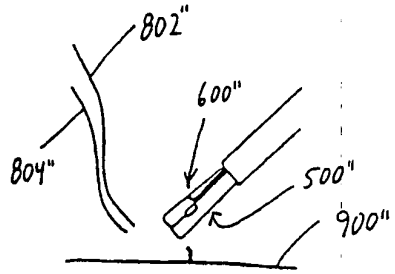

FIG. 49"

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A3

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08/478,477 7 June 1995 (07.06.95) US

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(72) Inventors: NICHOLSON, James; 14 Meadowdam Road, Lincoln, MA 01773 (US). HART, Rickey, D.; 118 Jefferson Street, North Attleboro, MA 02760 (US). RICE, John; 21 Red Rail Farm Lane, Lincoln, MA 01773 (US).

(74) Agent: POWSNER, David, J.; Choate, Hall & Stewart, Exchange Place, 53 State Street, Boston, MA 02109 (US).

(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

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With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

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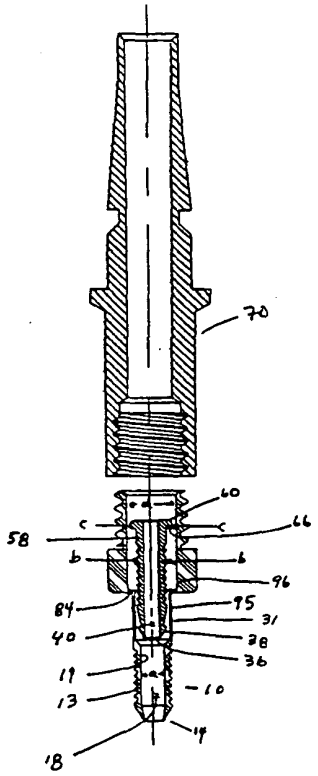
6 March 1997 (06.03.97)

(54) Title: SURGICAL SYSTEM AND METHOD FOR THE REATTACHMENT OF SOFT TISSUE TO BONE

(57) Abstract

The present invention is directed to novel surgical systems that include a combination of an improved bone fastener, suture grasping device and/or suture throw rundown instrument. The systems can be used, e.g., for endoscopic procedures to repair and reattach soft tissues. The systems include a bone fastener comprising an expandable member having an axial channel and an elongated element inserted into the axial channel. The expandable member is configured to be insertible into a bore drilled in bone. The member is expanded using a continuous, compressive force (i.e., pressure without impulse or impact). The expandable member is grasped at its distal end throughout the emplacement procedure and is axially released from an emplacement tool. The systems can further include a suture grasping device comprising a rigid, hollow shaft, a rod, a first elongate wire-like element, a second elongated wire-like element, and an actuation device. The systems further include a suture throw rundown element comprising a handle assembly having first and second handle members movably connected for movement relative to one another, an elongate rod releasably secured to the first handle member.



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INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 96/09088

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/04 A61B17/32 A61B17/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO,A,92 04874 (NICHOLSON ASSOCIATES INC) 2 April 1992	1-9
A	see page 13, line 28 - page 14, line 9; figures 1-12	10-12

Y	WO,A,95 02998 (INNOVASIVE DEVICES INC) 2 February 1995 cited in the application	1-9
A	see the whole document	10-12

A	GB,A,2 248 778 (BIOMET LTD) 22 April 1992 see page 4, line 33 - line 35; figures 2,3	3

A	US,A,4 988 351 (PAULOS LEON E ET AL) 29 January 1991 see figures 1,7	3

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2

Date of the actual completion of the international search	Date of mailing of the international search report
21 January 1997	31.01.97

Name and mailing address of the ISA	Authorized officer
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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 96/09088

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP,A,0 574 707 (UNITED STATES SURGICAL CORP) 22 December 1993 see column 6, line 18 - line 35	1
A	EP,A,0 611 557 (SMITH & NEPHEW DYONICS) 24 August 1994 see column 7, line 14 - line 43; figures 1,3,5,7	1-4,6
A	US,A,5 257 637 (EL GAZAYERLI MOHAMED M) 2 November 1993 see column 4, line 29 - line 40; figures 2,7-9	10
P,A	WO,A,95 29636 (INNOVASIVE DEVICES INC) 9 November 1995 cited in the application see the whole document	10-12

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INTERNATIONAL SEARCH REPORT

rnational application No.
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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 13-21
because they relate to subject matter not required to be searched by this Authority, namely:
Method for the treatment of the human body by surgery.
See Rule 39.1(iv) PCT.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter. nal Application No
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
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